CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-256

PRINTED LABELING
Desogestrel and Ethinyl Estradiol Tablets

0.15mg/0.03mg

6 Cyclic Tablet Dispensers x 21 Tablets

21 Day Regimen

NDC 51285-575-21

IMPORTANT:
This carton contains Detailed Patient Labeling and each Cyclic Tablet Dispenser contains the Brief Patient Labeling. Both should be included with each package dispensed to the patient.

PHARMACIST:
Please be sure to place one of the enclosed "Instructions" stickers on the cover of each binder and pouch at the time of dispensing.

DESIGNATED/pharmaceutical product

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
Desogestrel and Ethinyl Estradiol Tablets

0.15mg/0.03mg

Each rose-colored tablet contains
0.15 mg desogestrel and 0.03 mg ethinyl estradiol.

Usual Dosage:
One tablet daily as prescribed. See package insert.

Storage:
Store at controlled room temperature 15°-30°C (59°-86°F).

Duramed Pharmaceuticals, Inc.
Cincinnati, Ohio 45213 USA

Lot No.: 
Exp. Date:
Desogestrel and Ethinyl Estradiol Tablets

0.15mg/0.03mg

IMPORTANT:
This carton contains Detailed Patient Labeling and each Cyclic Tablet Dispenser contains the Brief Patient Labeling. Both should be included with each package dispensed to the patient.

PHARMACIST:
Please be sure to place one of the enclosed "Hormone" stickers on the cover of each blister and pouch at the time of dispensing.

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
Desogestrel and Ethinyl Estradiol Tablets
0.15mg/0.03mg

Each rose-colored tablet contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol. Each white tablet contains inert ingredients.

Usual Dosage:
One tablet daily as prescribed. See package insert.

DURAMED PHARMACEUTICALS, INC.
CINCINNATI, OHIO 45213 USA
C00286
ISS. 04/99
Desogestrel and Ethinyl Estradiol Tablets
0.15mg/0.03mg

12 only
21 Day Regimen

THIS PRODUCT (LIKE ALL ORAL CONTRACEPTIVES) IS INTENDED TO PREVENT PREGNANCY. IT DOES NOT PROTECT AGAINST HIV INFECTION (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES.

Contents: One cyclic tablet dispenser x 21 tablets
Brief Summary Patient Package Insert
Desogestrel and Ethinyl Estradiol Tablets
21 Day Regimen

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

MON TUE WED THU FRI SAT SUN
TUE WED THU FRI SAT SUN MON
WED THU FRI SAT SUN MON TUE
THU FRI SAT SUN MON TUE WED
FRI SAT SUN MON TUE WED THU
SAT SUN MON TUE WED THU FRI

21 Day Regimen Blister Card: Contains 21 round, rose-colored tablets in a blister card attached to a "credit card" dispenser. Each rose-colored tablet contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol.

Oral contraceptives also known as "birth control pills" or "the pill," are taken to prevent pregnancy, and when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of users is less than 3% per year when women who miss pills are included. For most women, oral contraceptives are free of serious or unpleasant side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely, but there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, high cholesterol
- have or have had clotting disorders, heart attack, stroke, anemia, chronic kidney disease, or liver tumors

Although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer lower-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Cigarette smoking increases the risk of serious cardiovascular risks associated with oral contraceptives. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised to stop smoking.

Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, headaches, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (venous phlebitis) or lungs (pulmonary embolism), and stroke or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack or angina pectoris) or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes, and subsequent serious medical consequences.
2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definitive association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although high blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed patient labeling given to you with your supply of pills. Notify your doctor or clinic if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some antibiotics and some antiarrhythmics may decrease oral contraceptive effectiveness.

There is conflict among studies regarding breast cancer and oral contraceptive use. Some studies have reported an increase in the risk of developing breast cancer, particularly at a younger age. This increased risk appears to be related to duration of use. The majority of studies have found no overall increase in the risk of developing breast cancer.
4. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed patient labeling given to you with your supply of pills. Notify your doctor or clinic if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as estrogens, as well as some contraceptives and some antibiotics may increase oral contraceptive effectiveness.

There is evidence among studies regarding breast cancer and oral contraceptive use. Some studies have reported an increased risk of developing breast cancer, particularly in younger age groups. The increased risk appears to be related to duration of use. The majority of studies have found no overall increase in the risk of developing breast cancer. Some studies have reported an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives. There is insufficient evidence to rule out the possibility that pills may cause such cancers.

Taking the pill provides some important non-cumulative benefits. These include lower pelvic infections, less menorrhagia, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your doctor or clinic. Your doctor or clinic will have a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and your doctor or clinic believes that it is a good medical practice to postpone it. You should be re-examined at least once a year while taking oral contraceptives. The detailed patient information labeling gives you further information on how to do this.

THIS PRODUCT (LIKE ALL ORAL CONTRACEPTIVES) IS INTENDED TO PREVENT PREGNANCY. IT DOES NOT PROTECT AGAINST TRANSMISSION OF HIV (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES SUCH AS CHLAMYDIA, GENITAL HERPES, GENITAL WARTS, GONORRHEA, HERPES SIMPLEX, AND SYphilis.

HOW TO TAKE THE PILLS

INFORMATION POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS

1. BE SURE TO READ THESE DIRECTIONS.
   Before you start taking your pills, anyone who is not sure what to do.

2. THE RIGHT WAY TO TAKE THE PILLS IS TO TAKE ONE Pill EVERY DAY AT THE SAME TIME.
   If you miss pills you could get pregnant. If you start the pack late,
   The more pills you miss, the more likely you are to get pregnant.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING. OR MAY FEEL SICK
   TO THEIR STOMACH DURING THE FIRST 3 days of PILLS.
   If you feel sick to your stomach, do not take the pill. The problem will
   Usually go away. If it doesn't go away, check with your doctor or clinic.

4. MISSED PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even
   when you make up these missed pills. On the days you take 2 pills to make up
   for missed pills, you could also feel a little sick to your stomach.

5. IF YOU HAVE VOMITING OR DIARRHEA, for any reason, or IF YOU TAKE
   SOME MEDICATIONS, including some antibiotics, your pills may not work as
   well. Use a back-up method (such as condoms, foam, or sponge) until you check
   with your doctor or clinic.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILLS, talk to your doc-
   tor or clinic about how to make pill-taking easier or about using another
   method of birth control.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNCERTAIN ABOUT THE INFORMATION
   IN THIS LEAFLET, call your doctor or clinic.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILLS. It is important
   to take it at about the same time every day.

2. LOOK AT YOUR PILL PACK TO SEE THAT IT HAS 21 PILLS.
   The 21 pills pack has 21 "active" (rosa-colored) pills (with hormones) to take
   for 3 weeks, followed by 1 week without pills.

3. ALSO FIND
   1) where on the pack to start taking the pills,
   2) in what order to take the pills (follow the arrows) and
   3) the week numbers as shown in the following example.

Example:

<table>
<thead>
<tr>
<th>21 Pill Pack</th>
<th>Rose-colored tablets</th>
</tr>
</thead>
</table>
4. **BE SURE YOU HAVE READY AT ALL TIMES:**
   ANY OTHER KIND OF BIRTH CONTROL (such as condoms, foam, or sponge) to use as a backup in case you miss pills.
   AN EXTRA FULL PACK.

**WHEN TO START THE FIRST PACK OF PILLS:**
You have a choice of which day to start taking your first pack of pills. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.

**DAY 1 START:**
1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost a month when you start bleeding begins). Place the day label strip on the cycle planner/benefit card over the area that has the days of the week (starting with Sunday) printed on the dispensing card.
2. Peel and place label here.

**Example:**

**Pick correct day label: THU FRI SAT SUN MON TUE WED:**

**Note:** If the first day of your period is a Sunday, you can skip steps 1 and 2.

3. Take the first "active" (rose-colored) pill of the first pack during the first 24 hours of your period.

4. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

**SUNDAY START:**
1. Take the first "active" (rose-colored) pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period starts on Sunday, start the pack at that same day.
2. Take another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days).
   Condoms, foam, or the sponge are good back-up methods of birth control.

**WHAT TO DO DURING THE MONTH:**
1. **TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THIS PACK IS EMPTY.**
   Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).
   Do not skip pills even if you do not have sex very often.
2. **WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:**
   Wait 7 days to start the next pack. You will probably have your period during that week. Be sure that no more than 7 days pass between 21-day packs.

**WHAT TO DO IF YOU MISS PILLS:**
If you **MISS 1** (rose-colored) "active" pill:
1. Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
2. Do not need to use a back-up birth control method if you have sex.
   If you **MISS 2** (rose-colored) "active" pills in a row in WEEK 1 OR WEEK 2 of your pack:
   1. Take 2 pills on the day you remember and 2 pills the next day.
   2. Then take 1 pill a day until you finish the pack.
   3. **YOU MAY BECOME PREGNANT** if you have sex 7 days after you miss pills.
   **YOU MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up method for these 7 days.
   If you **MISS 2** (rose-colored) "active" pills in a row in the 3rd WEEK:
   1. **If you are a Day 1 Starter:**
      THROW OUT the rest of the pill pack and start a new pack that same day.
   **If you are a Sunday Starter:**
      Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
   2. **YOU MUST NOT HAVE YOUR PERIOD this month but this is expected.** However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   3. **YOU MUST BECOME PREGNANT** if you have sex in the 7 days after you miss pills. **YOU MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.
   If you **MISS 3 OR MORE** (rose-colored) "active" pills in a row (during the first 3 weeks):
   1. **If you are a Day 1 Starter:**
      THROW OUT the rest of the pill pack and start a new pack that same day.
   **If you are a Sunday Starter:**
      Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
   2. **YOU MAY NOT HAVE YOUR PERIOD this month but this is expected.** However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   3. **YOU MUST BECOME PREGNANT** if you have sex in the 7 days after you missed pills. **YOU MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

**FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:**
Use a BACK-UP METHOD any time you have sex.
KEEP TAKING ONE (ROSE-COLORED) "ACTIVE" PILL EACH DAY UNTIL YOU CAN REACH YOUR DOCTOR OR CLINIC.
Sunday, start the pack that same day.

Use another method of birth control if you have sex any-
time from the Sunday you start your first pack until the next Sunday (7 days).

Condoms, foam, or the sponge are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH:
1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.
Do not skip pills even if you are spotting or bleeding between monthly peri-
ods or feel sick to your stomach (nausea).
Do not skip pills even if you do not have sex very often.

2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:
Wait 7 days to start the next pack. You will probably have your period during
this week. Be sure that no more than 7 days pass between 21-day packs.

WHAT TO DO IF YOU MISS PILLS:
If you MISS 1 (rose-colored) "active" pill:
1.  Take it as soon as you remember. Take the next pill at your regular time.
   This means you take 2 pills in 1 day.
2.  Do not need to use a back-up birth control method if you have sex.
   If you MISS 2 (rose-colored) "active" pills in a row in WEEK 1 OR WEEK 2 of your pack:
   1.  Take 2 pills on the day you remember and 2 pills the next day.
   2.  Then take 1 pill a day until you finish the pack.
   3.  You MAY BECOME PREGNANT if you have sex in the 2 days after you miss pills.
   You MUST use another birth control method (such as condoms, foam, or sponges) as a back-up method for those 7 days.
   If you MISS 2 (rose-colored) "active" pills in a row in THE 3RD WEEK:
   1.  If you are a Day 1 Starter:
      THROW OUT the rest of the pill pack and start a new pack that same day.
      If you are a Sunday Starter:
      Keep taking 1 pill every day until Sunday.
      On Sunday, THROW OUT the rest of the pack and start a new pack of pills that
      same day.
   2.  You may not have your period this month but this is expected. However, if you
      miss your period 2 months in a row, call your doctor or clinic because you
      may be pregnant.
   3.  You MAY BECOME PREGNANT if you have sex in the 2 days after you miss
      pills. You MUST use another birth control method (such as condoms, foam,
      or sponges) as a back-up method for those 7 days.
   If you MISS 3 OR MORE (rose-colored) "active" pills in a row (during the first 3 weeks):
   1.  If you are a Day 1 Starter:
      THROW OUT the rest of the pill pack and start a new pack that same day.
      If you are a Sunday Starter:
      Keep taking 1 pill every day until Sunday.
      On Sunday, THROW OUT the rest of the pack and start a new pack of pills that
      same day.
   2.  You may not have your period this month but this is expected. However, if you
      miss your period 2 months in a row, call your doctor or clinic because you
      may be pregnant.
   3.  You MAY BECOME PREGNANT if you have sex in the 2 days after you miss
      pills. You MUST use another birth control method (such as condoms, foam,
      or sponges) as a back-up method for those 7 days.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE
MISSED:
Use a BACK-UP METHOD anytime you have sex.
KEEP TAKING ONE (ROSE-COLORED) "ACTIVE" PILL EACH DAY until you can
reach your doctor or clinic.

CIBA-GEIGY CORPORATION
CINCINNATI, OHIO 45213 USA

93030
Brief Summary Patient Package Insert
Desogestrel and Ethinyl Estradiol Tablets
Is only
28 Day Regimen

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not provide protection against any infection (AIDS) and other sexually transmitted diseases.

MON TUE WED THU FRI SAT SUN TUE WED THU FRI SAT SUN MON TUE WED THU FRI SAT SUN MON TUE WED THU FRI SAT SUN MON TUE WED THU FRI

28 Day Regimen Blister Card, Contains 21 round rose-colored tablets and 7 round white tablets in a blister card attached to a "medic alert" enamel. Each rose-colored tablet contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol. Each white tablet contains inert ingredients.

Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy, and when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of large numbers of pill takers is less than 3% per year when women who miss pills are included. For most women, oral contraceptives are safe to use and are without serious side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability. The risks associated with using oral contraceptives have been significantly reduced if you:

- Smoke
- Have high blood pressure, diabetes, high cholesterol
- Have a family history of heart disease, stroke, angina, peptic ulcer, cancer of the breast or uterus, endometriosis or malformation of the bladder or uterus

Although cardiovascular disease risks may be increased with oral contraceptives use after age 40 in healthy, non-smoking women (even with the newest low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Cigarette smoking increases the risks of serious cardiovascular side effects from oral contraceptives use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is equiva lent in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

Most side effects of the pill are not serious. The most common side effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, headache, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that few of the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the leg (thromboembolus) or lungs (pulmonary embolism), blockage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack or severe pain) or other organs of the body. As mentioned above, smoking increases the risk of heart attack and stroke, two serious medical consequences.

2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.

3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed patient labeling given to you with your supply of pills. Notify your doctor or nurse if you notice any unusual physical discomfort while taking the pill. In addition, things such as weight loss or gain, as well as some anticonvulsants and some antibiotics may increase oral contraceptive effectiveness.

There is conflict among studies regarding breast cancer and oral contraceptive use. Some studies have reported an increased risk of developing breast cancer, particularly in a younger age. This increased risk appears to be related to duration of use. The majority of studies, however, have found no overall increase in the risk of developing breast cancer. Some studies have found an increase in the incidence of cancer among women taking oral contraceptives. However, the evidence is not consistent, and the balance may be
2. Liver tumors, which may rupture and cause severe bleeding. A possible but distant risk factor has been seen with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.

3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these rare side effects are discussed in the separate patient labeling given to you with your supply of pills. Notify your doctor or clinic if you notice any unusual physical disturbances while taking the pill. In addition, many such as acne, as well as some anticonvulsants and other anticonvulsants may increase oral contraceptive effectiveness.

There is controversy regarding breast cancer and oral contraceptives. Some studies have reported an increase in the risk of developing breast cancer, particularly in younger age. This increased risk appears to be related to duration of use. The majority of studies have found no overall increase in the risk of developing breast cancer. Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives. There is insufficient evidence to rule out the possibility that pills may cause such cancers.

Taking the pill provides some important non-contraceptive benefits. These include less painful menstruation, less menopausal bleeding and pain, fewer pelvic infections, and lower cancer risk of the ovaries and the lining of the uterus.

Be sure to discuss any medical condition you may have with your doctor or clinic. Your doctor or clinic will take your medical history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and your doctor or clinic believes it is a good medical practice to postpone it. You should be examined at least once a year while taking oral contraceptives. The detailed patient information labeling gives you further information which you should read and discuss with your doctor or clinic. This product (like all oral contraceptives) is intended to prevent pregnancy. IT DOES NOT PROTECT AGAINST TRANSMISSION OF HIV/AIDS AND OTHER SEXUALLY TRANSMITTED INFECTIONS SUCH AS CHLAMYDIA, GONORRHEA, HEPATITIS B, AND GENITAL HERPES.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER:

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:
   - before you start taking your pills.
   - anytime you are not sure what to do.

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.
   - If you miss a pill you may get pregnant. This includes missing the patch late. The more pills you miss, the more likely you are to get pregnant.
   -if you miss a pill you may get pregnant. This includes missing the patch late. The more pills you miss, the more likely you are to get pregnant.
   - if you feel sick to your stomach, do not stop taking the pill. The pill will usually go away. If it doesn't go away, check with your doctor or clinic.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS.
   - If you feel sick to your stomach, do not stop taking the pill. The pill will usually go away. If it doesn't go away, check with your doctor or clinic.

4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you missed one or two pills. If you missed one or two pills, you may feel a little bit sick to your stomach.

5. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, CALL YOUR DOCTOR OR CLINIC.

BEFORE YOU START TAKING YOUR PILLS:

1. CHOOSE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. IT IS IMPORTANT TO TAKE IT AT THE SAME TIME EVERY DAY.

2. LOOK AT YOUR PILL PACK TO SEE THAT IT HAS 28 PILLS:

   The 28-pill pack has 21 "active" (rose-colored) pills (with hormones) to take for 3 weeks, followed by 1 week of remainder (white) pills (without hormones).

3. ALSO FIND:
   1) where on the pack to start taking the pills.
   2) in what order to take the pills (below the arrows) and
   3) the week numbers as shown in the following example.

   **28 Pill Pack**
   **Example Only:**

   Rose-colored
   **Tablets**

   White Tablets
4. BE SURE YOU HAVE READY AT ALL TIMES
ANOTHER KIND OF BIRTH CONTROL, SUCH AS CONDOMS, FOAM, OR SPONGE TO USE AS A BACK-UP IF YOU MISS PILLS.
AN EXTRA, FULL PILL PACK

WHEN TO START THE FIRST PACK OF PILLS:
You have a choice of which day to start taking your first pack of pills. Discuss with your doctor or clinic which is the best day for you. Pick a same-day method which will be easy to remember.

DAY 1 START:
1. Pick the day label strip that starts with the first day of your period (the day you start bleeding or spotting, if it is not menstruation the bleeding begins).
2. Place this day label strip on the cyclic pill dispenser card over the area that has the days of the week starting with Sunday printed on the dispensing card.

Example:

Pick correct day label
THUR FRI SAT SUN MON TUE WED

Note: If the first day of your period is a Sunday, you can skip steps 1 and 2.
3. Take the first “active” (rose-colored) pill of the first pack during the first 24 hours of your period.
4. You will not need to use the backs-up method of birth control, since you are starting the pill at the beginning of your period.

SUNDAY START:
1. Take the first “active” (rose-colored) pill of the first pack on the Sunday after your period begins, if you are still bleeding. If your period begins on Sunday, start the pack the same day.
2. Use another method of birth control as a backs-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge are good backs-up methods of birth control.

WHAT TO DO DURING THE MONTH:
1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.
   Do not skip pills even if you are spotting or bleeding between menstrual periods or feel sick to your stomach (nausea).
   Do not skip pills even if you do not have sex very often.
2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:
   Start the next pack on the day after your last “reminder” pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS:
If you MISS 1 (rose-colored) “active” pill:
1. Take it as soon as you remember. Take the next pill at your regular time.
   This means you take 2 pills in 1 day.
2. You do not need to use a backs-up birth control method if you have sex.
   If you MISS 2 (rose-colored) “active” pills in a row in WEEK 1 OR WEEK 2 of your pack:
   1. Take 2 pills on the day you remember and 2 pills the next day.
   2. Then take 1 pill a day until you finish the pack.
   3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
      You MUST use another birth control method (such as condoms, foam, or sponge) as a backs-up method for those 7 days.
   If you MISS 2 (rose-colored) “active” pills in a row in the 3RD WEEK:
   1. If you are a Day 1 Starter:
      THROW OUT the rest of the pill pack and start a new pack that same day.
   If you are a Sunday Starter:
      Keep taking 1 pill every day until Sunday.
   On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
   2. You may not have your period this month but this is expected.
      However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
      You MUST use another birth control method (such as condoms, foam, or sponge) as a backs-up method for those 7 days.
   If you MISS 3 OR MORE (rose-colored) “active” pills in a row (during the last 3 weeks):
   1. If you are a Day 1 Starter:
      THROW OUT the rest of the pill pack and start a new pack that same day.
   If you are a Sunday Starter:
      Keep taking 1 pill every day until Sunday.
   On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
   2. You may or may not have your period this month but this is expected.
      However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
      You MUST use another birth control method (such as condoms, foam, or sponge) as a backs-up method for those 7 days.

A REMINDER FOR THOSE ON 28-DAY PACKS:
If you forget any of the 7 (white) “reminder” pills in Week 4:
THROW AWAY the pills you missed.
Keep taking 1 pill each day until the pack is empty.
You do not need a backs-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:
Use a BACK-UP METHOD anytime you have sex.

---

Use this information to help you keep track of when to take your pills.
WHAT TO DO DURING THE MONTH:

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNLESS THE PACK IS EMPTY. Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea). Do not skip pills if you do not have sex very often.

2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS: Start the next pack on the day after your last "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS:

If you MISS 1 (rose-colored) "active" pill:
1. Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
2. You do not need to use a back-up birth control method if you have sex.
3. If you miss 2 (rose-colored) "active" pills in a row in WEEK 1 OR WEEK 2 of your pack:
   1. Take 2 pills on the day you remember and 2 pills the next day.
   2. Then take 1 pill a day until you finish the pack.
   3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another form of birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.
   4. If you miss 2 (rose-colored) "active" pills in a row in WEEK 3 or WEEK 4:
      1. If you are a Day 1 Starter:
         a. THROW OUT the rest of the pill pack and start a new pack that same day.
      2. If you are a Sunday Starter:
         a. Keep taking 1 pill every day until Sunday.
         b. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
   5. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   6. If you have sex in the 7 days after you missed pills, you MUST use another form of birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

A REMINDER FOR THOSE ON 28-DAY PACKS:
If you forget any of the 7 (white) "reminder" pills in Week 4:
THROW AWAY the pills you missed.
Keep taking 1 pill each day until the pack is empty.
You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:
Use a BACK-UP METHOD anytime you have sex.
KEEP TAKING ONE (ROSE-COLORED) "ACTIVE" PILL EACH DAY until you can reach your doctor or clinic.
DETAILED PATIENT LABELING
Desogestrel and Ethinyl Estradiol Tablets
28 and 21 Day Regimens

THIS PRODUCT (LIKE ALL ORAL CONTRACEPTIVES) IS INTENDED TO PREVENT PREGNANCY. IT DOES NOT PROTECT AGAINST HIV INFECTION (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES.

13 only
**PLEASE NOTE:** This labeling is revised from time to time to include important new medical information becomes available. Therefore, please review this labeling carefully.

The following oral contraceptive products contain a combination of progesterogen and estrogen, the two kinds of female hormones:

**Desogestrel and Ethinyl Estradiol Tablets 28 Day Regimen blister Card**
Each rose-colored tablet contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol. Each white tablet contains inert ingredients.

**Desogestrel and Ethinyl Estradiol Tablets 21 Day Regimen blister Card**
Each rose-colored tablet contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol.

**INTRODUCTION**

Any woman who considers using oral contraceptives (the birth control pill or the pill) should understand the benefits and risks of using this form of birth control. This patient labeling will give you much of the information you will need to make this decision and will also help you determine if you are at risk of experiencing any of the serious side effects of the pill. It will tell you how to use the pill properly so that it will be as effective as possible. However, this labeling is not a replacement for a careful discussion between you and your doctor or clinician. You should discuss the information provided in this labeling with him or her, both when you first start taking the pill and during your revisit. You should also follow your doctor's or clinician's advice regard to regular check-ups while you are on the pill.

**EFFECTIVENESS OF ORAL CONTRACEPTIVES**

Oral contraceptives or “birth control pills” or “the pill” are used to prevent pregnancy and are more effective than other non-surgical methods of birth control. When they are taken correctly, the chance of becoming pregnant is less than 1% (1 pregnancy per 100 women per year if used correctly) and using them as prescribed may stop missing any pills. Typical failure rates are actually 3% per year.

The chance of becoming pregnant increases with missed pills during a menstrual cycle.

In comparison, typical failure rates for other non-surgical methods of birth control during the first year of use are as follows:

- Implant: <1%
- Injections: <1%
- IUD: 1 to 2%
- Diaphragm with spermicide: 8%
- Spermicides alone: 21%
- Vaginal sponge: 18 to 35%
- Cervical Cap: 18 to 35%
- Condom alone (male): 12%
- Condom alone (female): 27%
- Periodic abstinence: 25%
- No methods: 35%

**WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES**

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years at age. Women who use oral contraceptives are strongly advised not to smoke.

Some women should not use the pill. For example, you should not take the pill if you are pregnant or think you may be pregnant. You should also not use the pill if you have any of the following conditions:

- A history of heart attack or stroke
- Blood clots in the legs (thromboembolism), lungs (pulmonary embolism), or eyes
- A history of blood clots in the deep veins of your legs
- Chest pain (angina pectoris)
- Known or suspected breast cancer or cancer of the lining of the uterus, cervix, or vagina
- Unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- Vomiting of the whites of the eyes or pain of the skin (jaundice) during pregnancy or during previous use of the pill
- Liver tumor (benign or cancerous)
- Known or suspected pregnancy

Tell your doctor or clinician if you have ever had any of these conditions. Your doctor or clinician can recommend a safer method of birth control.

**OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES**

Tell your doctor or clinician if you have or have had:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram
- Diabetes
- Elevated cholesterol or triglycerides
- High blood pressure
- Migraine or other headaches or epilepsy
- Mental depression
- Gallbladder, heart or kidney disease
- History of scanty or irregular menstrual periods

Women with any of these conditions should be checked over by your doctor or clinician if they choose to use oral contraceptives. Also, be sure to inform your doctor or clinician if you smoke or are on any medications.

**RISKS OF TAKING ORAL CONTRACEPTIVES**

1. Risk of developing blood clots

Blood clots and blockage of blood vessels are one of the most serious side effects of taking oral contraceptives and can cause death or serious disability. In particular, a clot in one of the legs can cause thromboembolism and a clot that travels to the lungs can cause a sudden blocking of the vessel carrying blood to the lungs. These risks are greater with desogestrel-containing oral contraceptives, such as desogestrel and ethinyl estradiol tablets, than with other low-dose pills. Rarely, clots occur in the blood vessels of the eyes and may cause blindness, double vision, or impaired vision.

If you use oral contraceptives and need surgical or dental procedures such as tooth拔除 or tooth extraction, you must be at risk of developing blood clots. You should consult your doctor or clinician before stopping oral contraceptives three to four weeks before surgery and will only stop taking oral contraceptives for two weeks after surgery or during bed rest. You should also not take oral contraceptives soon after delivery of a baby. It is advisable to wait for at least four weeks after delivery if you are not breast feeding or four weeks after a second trimester abortion. If you are breast feeding, you should wait until you have weaned your child before using this pill. (See also the section on Breast Feeding in General Precautions.)

The risk of clotting disease in oral contraceptive users may be higher in users of high dose pills and may be greater with longer duration of oral contraceptive use. In addition, some of these increased risks may continue for a number of years after stopping oral contraceptives. The risk of abnormal blood clotting increases with the number of years in birth control pill use, oral contraceptives, and but the increased risk from oral contraceptive use appears to be present at all ages. For women aged 20 to 44 it is estimated that about 1 in 2,000 using oral contraceptives will be hospitalized in any year because of abnormal clotting.

Among non-contraceptive users of the same age group, about 1 in 20,000 would be hospitalized each year. For oral contraceptive users in general, it has been estimated that in women between the ages of 15 and 34 the risk of death due to a circulatory disorder is about 1 in 12,000 per year; whereas for non-users the risk is about 1 in 50,000 per year. In the age group 35 to 44, the risk is estimated to be about 1 in 2,500 per year for oral contraceptive users and about 1 in 10,000 per year for nonusers.

2. Heart attacks and strokes

Oral contraceptives may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability. Smoking greatly increases the possibility of suffering heart attacks and strokes. Furthermore, smoking and the use of oral contraceptives greatly increase the chances of developing and dying of heart disease.

3. Gallbladder disease

Oral contraceptive users probably have a greater risk than non-users of having gallbladder disease. Although this risk may be related to pills containing high doses of estrogen.

4. Liver tumors

In rare cases, oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with the pill and liver cancers in two studies, in which a few women who developed these very rare cancers were found to have used oral contraceptives for long periods. However, liver cancers are rare.

5. Cancer of the reproductive organs and breasts

There is conflict among studies regarding breast cancer and oral contraceptive use. Some studies have reported an increase in the risk of developing breast cancer, particularly at a younger age. This increased risk appears to be related to duration of use. The majority of studies have found no overall increase in the risk of developing breast cancer.

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives. There is sufficient evidence to rule out the possibility that pills may cause such cancers.

**ESTIMATED RISK OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY**

All methods of birth control and pregnancy are associated with a risk of developing certain diseases which may lead to disability or death. An estimate of the number of deaths associated with different methods of birth control and pregnancy has been calculated and is shown in the following table.

**ANNUAL NUMBER OF BIRTH-RELATED OR METHOD-RELATED DEATHS ASSOCIATED WITH CONDOMS OF FERTILITY CONTROL AMONG 100,000 WOMEN, BY FERTILITY CONTROL METHOD ACCORDING TO AGE**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No fertility control methods*</td>
<td>7.0</td>
<td>7.4</td>
<td>9.1</td>
<td>14.8</td>
<td>25.7</td>
<td>28.2</td>
</tr>
<tr>
<td>Oral contraceptives smoker**</td>
<td>0.3</td>
<td>0.5</td>
<td>0.9</td>
<td>1.9</td>
<td>13.8</td>
<td>21.6</td>
</tr>
<tr>
<td>Oral contraceptives non-smoker**</td>
<td>2.2</td>
<td>3.4</td>
<td>6.6</td>
<td>13.5</td>
<td>51.1</td>
<td>117.2</td>
</tr>
<tr>
<td>IUD**</td>
<td>0.8</td>
<td>0.8</td>
<td>1.0</td>
<td>1.0</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Condom*</td>
<td>1.1</td>
<td>1.6</td>
<td>0.7</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Diaphragm/spermicide*</td>
<td>1.9</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>2.2</td>
<td>2.8</td>
</tr>
<tr>
<td>Pericystic abstinence*</td>
<td>2.5</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>2.9</td>
<td>3.6</td>
</tr>
</tbody>
</table>

* Deaths are birth related
** Deaths are method related

In the preceding table, the risk of death from any birth control method is less than the risk of childbirth, except for oral contraceptive users over the age of 35 who smoke and pill users over the age of 40 even if they do not smoke. It can be seen in the table that for women aged 15 to 35, the risk of death was highest with pregnancy (7-26 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death was always lower than that associated with pregnancy for any age group, although over the age of 40, the risk increases to 32 deaths per 100,000 women, compared to 23 associated with smoking.
pregnancy at that age. However, for pill users who smoke and are over the age of 35, the estimated number of deaths exceeds those for other methods of birth control. If a woman is over the age of 40 and smokes, her estimated risk of death is four times higher (117/100,000 women) than the estimated risk associated with pregnancy (26/100,000 women) in that age group.

The suggestion that women over 40 who do not smoke should not take oral contraceptives is based on information obtained from older, higher-dose pills. An Advisory Committee of the FDA discussed this issue in 1989 and recommended that the benefits of low-dose oral contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks.

**WARNING SIGNS**

If any of these adverse effects occur while you are taking oral contraceptives, call your doctor or clinic immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible clot in the lung).
- Pain in the calf (indicating a possible clot in the leg).
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack).
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke).
- Sudden partial or complete loss of vision (indicating a possible clot in the eye).
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your doctor or clinic to show you how to examine your breasts).
- Severe pain or tenderness in the stomach area (indicating a possibly ruptured liver tumor).
- Difficulty in breathing, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression).
- Jaundice or a yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark colored urine, or light colored bowel movements (indicating possible liver problems).

**SIDE EFFECTS OF ORAL CONTRACEPTIVES**

1. Vaginal bleeding

Irregular vaginal bleeding or spotting may occur while you are taking the pills. Irregular bleeding may vary from slight spotting between menstrual periods to breakthrough bleeding which is a flow much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle or lasts for more than a few days, talk to your doctor or clinic.

2. Contact lenses

If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or clinic.

3. Fluid retention

Oral contraceptives may cause edema (fluid retention) with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your doctor or clinic.

4. Melasma

A spotty darkening of the skin is possible, particularly of the face, which may persist.

5. Other side effects

Other side effects may include nausea and vomiting, change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal infections.

If any of these side effects bother you, call your doctor or clinic.

**GENERAL PRECAUTIONS**

1. Missed periods and use of oral contraceptives before or during early pregnancy

There may be times when you may not menstruate regularly after you have completed a cycle of pills. If you have taken your pills regularly and miss one menstrual period, continue taking your pills for the next cycle but be sure to inform your doctor or clinic before doing so. If you have not taken the pills daily as instructed and missed a menstrual period, you may be pregnant. If you missed two consecutive menstrual periods, you may be pregnant. Check with your doctor or clinic immediately to determine whether you are pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant, but continue to use another method of contraception.

There is no conclusive evidence that oral contraceptive use is associated with an increase in birth defects, when taken inadvertently during early pregnancy.

Previously, a few studies had reported that oral contraceptives might be associated with birth defects, but those findings have not been seen in more recent studies. Nevertheless, oral contraceptives or any other drugs should not be used during pregnancy unless clearly necessary and prescribed by your doctor or clinic. You should check with your doctor or clinic about risks to your unborn child of any medication taken during pregnancy.

2. While breast feeding

If you are breast feeding, consult your doctor or clinic before starting oral contraceptives. Some of the drug will be passed on to the child in the milk. A few adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. In addition, oral contraceptives may decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breast feeding. You should use another method of contraception since breast feeding provides only partial protection from becoming pregnant and this partial protection decreases significantly as you breast feed for longer periods of time. You should consider starting oral contraceptives only after you have weaned your child completely.
3. Laboratory tests
   If you are scheduled for any laboratory tests, tell your doctor or clinic you are taking birth control pills. Certain blood tests may be affected by birth control pills.

4. Drug interactions
   Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include rifampin, drugs used for epilepsy such as barbiturates (for example, phenobarbital), anticonvulsants such as carbamazepine (Tegretol is one brand of this drug); phenytoin (Dilantin is one brand of this drug); phenylbutazone (Butazolidin is one brand); and possibly certain antibiotics. You may need to use additional contraception when you take drugs which can make oral contraceptives less effective.

5. Sexually transmitted diseases
   This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:
1. BE SURE TO READ THESE DIRECTIONS:
   Before you start taking your pills.
   Anytime you are not sure what to do.
2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.
   If you miss pills, you could get pregnant. This includes the last day of the pack.
   The more pills you miss, the more likely you are to get pregnant.
3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS.
   If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn’t go away, check with your doctor or clinic.
4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.
5. IF YOU HAVE VOMITING OR DIARRHEA, for any reason, OR IF YOU TAKE SOME MEDICINES, including some antibiotics, your pills may not work as well.
   Use a back-up method (such as condoms, foam, or sponge) until you check with your doctor or clinic.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic about how to make pill-taking easier or about using another method of birth control.
7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or clinic.

BEFORE YOU START TAKING YOUR PILLS:
1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at the same time every day.
2. LOOK AT YOUR PILLS PACK TO SEE IF IT HAS 21 OR 28 PILLS.
   The 21-pill pack has 21 “active” (rose-colored) pills (with hormones) to take for 3 weeks, followed by 1 week without pills.
   The 28-pill pack has 21 “active” (rose-colored) pills (with hormones) to take for 3 weeks, followed by 1 week of reminder (white) pills (without hormones).
3. ALSO FIND:
   1. where on the pack to start taking the pills,
   2. in what order to take the pills (follow the arrows) and
   3. the week numbers printed on the pack.

![Example Pill Pack]

4. BE SURE YOU HAVE READY AT ALL TIMES:
   ANOTHER KIND OF BIRTH CONTROL (such as condoms, foam, or sponge) to use as a back-up in case you miss pills.
   AN EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS:
You have a choice of which day to start taking your first pack of pills. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.
DAY 1 START:
1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins.)
2. Place this day label strip in the cycle tablet dispenser over the area that has the days of the week (starting with Sunday). Printed on the blister card.

Pick Correct Day Label


Peel and store label here
BEFORE YOU START TAKING YOUR PILLS:

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at about the same time every day.

2. LOOK AT YOUR PILL PACK TO SEE IF IT HAS 21 OR 28 PILLS:
   - The 21-pill pack has 21 "active" (rose-colored) pills with hormones to take for 3 weeks, followed by 1 week without pills.
   - The 28-pill pack has 21 "active" (rose-colored) pills with hormones to take for 3 weeks, followed by 1 week of remainder (white) pills without hormones.

3. ALSO FIND:
   - 1) where on the pack to start taking the pills,
   - 2) in what order to take the pills (follow the arrows)
   - 3) the week numbers printed on the pack.

4. BE SURE YOU HAVE READY AT ALL TIMES:
   - ANOTHER KIND OF BIRTH CONTROL (such as condoms, foam, or sponge) to use as a back-up in case you miss pills.
   - AN EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS:
You have a choice of which day to start taking your first pack of pills. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins.)
2. Place this day label strip in the cycle tablet dispenser over the area that has the days of the week (starting with Sunday) printed on the blister card.

Pick Correct Day Label

Note: If the first day of your period is a Sunday, you can skip steps #1 and #2.

3. Take the first "active" (rose-colored) pill of the first pack during the first 24 hours of your period.
4. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.
SUNDAY START:
1. Take the first "active" (rose-colored) pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. Use another method of birth control (as a back-up) if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH:
1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.
   Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).
   Do not skip pills even if you do not have sex very often.
2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:
   21 pills:
   Wait 7 days to start the next pack. You will probably start your period during that week. Be sure that no more than 7 days pass between 21-day packs.
   28 pills:
   Start the next pack on the day after your last "reminder" pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS:
If you MISS 1 (rose-colored) "active" pill:
1. Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
2. You do not need to use a back-up birth control method if you have sex.
   If you MISS 2 (rose-colored) "active" pills in a row in WEEK 1 OR WEEK 2 of your pack:
   1. Take 2 pills on the day you remember and 2 pills the next day.
   2. Then take 1 pill a day until you finish the pack.
   3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.
   If you MISS 2 OR MORE (rose-colored) "active" pills in a row in WEEK 3:
   1. If you are a Day 1 Starter:
      THROW OUT the rest of the pill pack and start a new pack that same day.
   2. If you are a Sunday Starter:
      Take 1 pill every day until Sunday.
      On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
   3. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   4. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
      You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.
   If you MISS 3 OR MORE (rose-colored) "active" pills in a row (during the first 3 weeks):
   1. If you are a Day 1 Starter:
      THROW OUT the rest of the pill pack and start a new pack that same day.
   2. If you are a Sunday Starter:
      Take 1 pill every day until Sunday.
      On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
   3. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
   4. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
      You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

A REMINDER FOR THOSE ON 28 DAY PACKS:
If you forget any of the 7 [white] "reminder" pills in Week 4:
THROW AWAY the pills you missed.
Keep taking 1 pill each day until the pack is empty.
You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:
Use a BACK-UP METHOD anytime you have sex.
KEEP TAKING THE ONE (rose-colored) "ACTIVE" PILL EACH DAY until you can reach your doctor or clinic.

PREGNANCY DUE TO PILL FAILURE
The incidence of pill failure resulting in pregnancy is approximately one percent (i.e., one pregnancy per 100 women per year) if taken every day as directed, but more typical failure rates are about 3%. If failure does occur, the risk to the fetus is minimal.

PREGNANCY AFTER STOPPING THE PILL
There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and desire pregnancy.
There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.
that same day.
2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

A REMINDER FOR THOSE ON 28 DAY PACKS:
If you forget any of the 7 [white] "reminder" pills in Week 4:
THROW AWAY the pills you missed.
Keep taking 1 pill each day until the pack is empty.
You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:
Use a BACK-UP METHOD anytime you have sex.
KEEP TAKING ONE [rose-colored] "ACTIVE" PILL EACH DAY until you can reach your doctor or clinic.

PREGNANCY DUE TO PILL FAILURE
The incidence of pill failure resulting in pregnancy is approximately one percent (i.e., one pregnancy per 100 women per year) if taken every day as directed, but more typical failure rates are about 3%. If failure does occur, the risk to the fetus is minimal.

PREGNANCY AFTER STOPPING THE PILL
There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you begin menstruating regularly once you have stopped taking the pill and desire pregnancy.
There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

OVERDOSE
Serious ill effects have not been reported following ingestion of large doses of oral contraceptives by young children. Overdose may cause nausea and withdrawal bleeding in females. In case of overdose, contact your doctor, clinic or pharmacist.

OTHER INFORMATION
Your doctor or clinic will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and your doctor or clinic believes that it is a good medical practice to postpone it. You should be reexamined at least once a year. Be sure to inform your doctor or clinic if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your doctor or clinic because this is a time to determine if there are early signs or side effects of oral contraceptive use.
Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others who may want birth control pills.

HEALTH BENEFITS FROM ORAL CONTRACEPTIVES
In addition to preventing pregnancy, use of combination oral contraceptives may provide certain benefits. They are:
• Menstrual cycles may become more regular
• Blood flow during menstruation may be lighter and less iron may be lost. Therefore, anemia due to iron deficiency is less likely to occur.
- Pain or other symptoms during menstruation may be encountered less frequently.
- Ectopic (tubal) pregnancy may occur less frequently.
- Noncancerous cysts or lumps in the breast may occur less frequently.
- Acute pelvic inflammatory disease may occur less frequently.
- Oral contraceptive use may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the lining of the uterus.

If you want more information about birth control pills, ask your doctor, clinic or pharmacist. They have a more technical leaflet called the Professional Labelling, which you may wish to read. The Professional Labelling is also published in a book entitled Physicians' Desk Reference, available in many book stores and public libraries.
Desogestrel and Ethinyl Estradiol Tablets

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

For use only for a 21-day pill cycle.
DESCRIPTION
The 28 and 21 Day Regimen tablet contains desogestrel and ethinyl estradiol in a ratio of 28:21. Each tablet contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol. The tablets are round, white with black marking "CPR 28D" on one side and "CPR 28" on the other.

DESGESTREL

ETHINYL ESTRADIOL

M.W. 310.48
M.W. 296.41

CLINICAL PHARMACOLOGY
Pharmacokinetics
Desogestrel is rapidly and almost completely absorbed and converted into 3-keto-desogestrel, its biologically active metabolite. Following oral administration, the relative bioavailability of desogestrel, as measured by urinary levels of 3-keto-desogestrel, is approximately 74%.

In the first cycle of use after a single desogestrel and ethinyl estradiol tablet, maximum concentrations of 3-keto-desogestrel of 2.86 ± 1.36 ng/mL (mean ± SD) are reached at 1.4 ± 0.7 hours. The area under the curve (AUC) of 3-keto-desogestrel is 52.4 ± 54.6 ng·h/mL. The elimination half-life of 3-keto-desogestrel is approximately 5.3 hours.

Pharmacodynamics
Desogestrel is rapidly and almost completely absorbed and converted into 3-keto-desogestrel, its biologically active metabolite. Following oral administration, the relative bioavailability of desogestrel, as measured by urinary levels of 3-keto-desogestrel, is approximately 74%.

In the first cycle of use after a single desogestrel and ethinyl estradiol tablet, maximum concentrations of 3-keto-desogestrel of 2.86 ± 1.36 ng/mL (mean ± SD) are reached at 1.4 ± 0.7 hours. The area under the curve (AUC) of 3-keto-desogestrel is 52.4 ± 54.6 ng·h/mL. The elimination half-life of 3-keto-desogestrel is approximately 5.3 hours.

Pharmacodynamics
Desogestrel is rapidly and almost completely absorbed and converted into 3-keto-desogestrel, its biologically active metabolite. Following oral administration, the relative bioavailability of desogestrel, as measured by urinary levels of 3-keto-desogestrel, is approximately 74%.

In the first cycle of use after a single desogestrel and ethinyl estradiol tablet, maximum concentrations of 3-keto-desogestrel of 2.86 ± 1.36 ng/mL (mean ± SD) are reached at 1.4 ± 0.7 hours. The area under the curve (AUC) of 3-keto-desogestrel is 52.4 ± 54.6 ng·h/mL. The elimination half-life of 3-keto-desogestrel is approximately 5.3 hours.

INDICATIONS AND USAGE
Desogestrel and ethinyl estradiol tablets are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. Oral contraceptives are highly effective. When compared to the typical annual pregnancy rates for women of combination oral contraceptives and other methods of contraception, the efficacy of these contraceptive methods, except sterilization, depends upon the reliability with which they are used. Correct and consistent use of these methods can result in lower failure rates.

<table>
<thead>
<tr>
<th>Method</th>
<th>Lowest Expected</th>
<th>Typical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Contraceptives</td>
<td>(8%)</td>
<td>(8%)</td>
</tr>
<tr>
<td>Combined</td>
<td>0.1</td>
<td>3</td>
</tr>
<tr>
<td>Progestin only</td>
<td>0.5</td>
<td>N/A**</td>
</tr>
<tr>
<td>Desogestrel with spermicidal</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>cream or jelly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spironolactone alone ( creams,</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>creams, gels, jellies, vaginal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>suppositories and vaginal film</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal Sponge coagulants</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>20</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Injection: depot</td>
<td>0.2</td>
<td>0.05</td>
</tr>
<tr>
<td>Combination with spermicides</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>1100 micrograms+ coagulants</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>coagulon 200A</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Contraceptives without spermicides</td>
<td>5</td>
<td>21</td>
</tr>
</tbody>
</table>

Note: The failure rates listed above refer to studies conducted in the first year of continuous use. The failure rates are based on the percentage of women who experience an accidental pregnancy while using the contraceptive method. The percentages are the result of studies conducted in the United States and Canada. Failure rates for other populations may vary.

For the most accurate and up-to-date information, please consult the product's package insert or contact your healthcare provider.
INDICATIONS AND USAGE

Oral contraceptives are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. Oral contraceptives are highly effective. Table 1 lists the typical accidental pregnancy rates for users of contraception and other methods of contraception. The efficacy of these contraceptive methods, except sterilization, depends upon the reliability with which they are used. Correct and consistent use of these methods can result in lower failure rates.

<table>
<thead>
<tr>
<th>Method</th>
<th>Lowest Expected</th>
<th>Typical</th>
</tr>
</thead>
<tbody>
<tr>
<td>(No Contraceptive)</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Oral Contraceptives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>progestin only</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>combined</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Diaphragm with spermicide</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Sponge alone (foam, crease, etc.)</td>
<td>0.09</td>
<td>0.09</td>
</tr>
<tr>
<td>Vaginal suppositories and vaginal lavage</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Birth control pills</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Depo-Provera®</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Ejaculated spermicides and semen</td>
<td>1.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Condoms</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>0.10</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Adapted from RA. Hatcher, et al. Table 5-2 (1994) ref. #1

In a clinical trial with desogestrel and ethinyl estradiol tablets, 1,195 subjects completed 11,856 cycles and a total of 18 pregnancies were reported. This represents an overall user-fertility (typical user-fertility) pregnancy rate of 1.12 per 100 women-years. This rate includes patients who did not take the drug correctly.

CONTRAINDICATIONS

Oral contraceptives like desogestrel and ethinyl estradiol tablets should not be used in women who currently have the following conditions:

- Thrombophilia or thromboembolic disorders
- A past history of deep vein thrombophlebitis or thromboembolic disorders
- Cerebrovascular or coronary artery disease
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Hepatic adenomas or carcinomas
- Known or suspected pregnancy

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasms and gallbladder disease, although the role of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of mortality and morbidity increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemia, obesity and diabetes. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

The information contained in this package insert is derived from studies carried out in patients who used oral contraceptives with formulations of higher doses of estrogens and progestogens than those in common use today. The effect of long-term use of the oral contraceptives with formulations of lower doses of both estrogens and progestogens remains to be determined.

Throughout this labeling, epidemiological studies reported are of two types: retrospective or case control studies and prospective or cohort studies. Case control studies provide a measure of the relative risk of a disease, namely, a ratio of the experience of a disease among oral contraceptive users to that among nonusers. The relative risk does not provide information on the actual clinical occurrence of a disease. Cohort studies provide a measure of attributable risk, which is the difference in the incidence of disease between oral contraceptive users and nonusers. The attributable risk does provide information on the actual clinical occurrence of a disease.
Oral contraceptives may complicate the effects of well-known risk factors, such as hypertension, diabetes, hypercholesterolemia, age, and obesity (12). In particular, some progestogen effects are known to increase LDL cholesterol and cause glucose intolerance, while estrogens may increase a state of hyperinsulinemia (14-18). Oral contraceptives have been shown to increase blood pressure among users (see section 9 in warnings). Similar risks on risk factors may be associated with an increased risk of heart disease. Oral contraceptives must be used with caution in women with cardiovascular disease risk factors. Desogestrel has minimal androgenic activity (see CLINICAL PHARMACOLOGY), and there is some evidence that the risk of myocardial infarction associated with oral contraceptives is lower when the progesteron has minimal androgenic activity than when the activity is greater (10).

b) Thromboembolism

An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. Data from case-control and cohort studies report that oral contraceptives containing desogestrel are associated with a three-fold increase in the risk of venous thromboembolic disease as compared to other low-dose (containing less than 50 mcg of estrogen) pills containing other progestins. According to these studies, this three-fold risk increases the yearly occurrence of venous thromboembolic disease by about 10-15 cases per 100,000 women.

Earlier case control studies on older formulations have found the relative risk of users compared to nonusers to be 3.5 for the first episode of superficial venous thrombosis, 4 to 11 for deep vein thrombosis or pulmonary embolism, and 1.5 to 6 for women with predisposing conditions for venous thromboembolic disease (2,3,19-34). Cohort studies have shown the relative risk to be somewhat lower, about 3 for new cases and about 4.5 for new cases requiring anticoagulation (25). The risk of thromboembolic disease associated with oral contraceptives is not related to length of use and disappears after pill use is stopped (2).

A two- to three-fold increase in relative risk of post-operative thromboembolic complications has been reported with the use of oral contraceptives (9). The relative risk of venous thrombosis in women who have predisposing conditions is twice that of women without such medical conditions (25). In feasible, oral contraceptives should be discontinued at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thromboembolism, oral contraceptives should be started no earlier than four weeks after delivery in women who elect not to breast feed.

c) Gastrointestinal disorders

Oral contraceptives have been shown to increase both the relative and attributable risks of gastrointestinal events (thrombotic and hemorrhagic strokes) although, in general, the risk is greatest among older (>35 years). Hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both types of strokes, and smoking was estimated to increase the risk of stroke (27-29).

In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for hemorrhagic strokes to 14 for users with severe hypertension (30). The relative risk of hemorrhagic strokes is reported to be 1.2 for nonsmokers who used oral contraceptives. 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for non-smokers and 2.7 for users with severe hypertension (30). The attributable risk is greater in older women (2).

d) Atherosclerotic vascular diseases

Oral contraceptives have shown to increase both the relative and attributable risks of cardiovascular events (thrombotic and hemorrhagic strokes) although, in general, the risk is greatest among older (>35 years). Hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both types of strokes, and smoking was estimated to increase the risk of stroke (27-29).

In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for hemorrhagic strokes to 14 for users with severe hypertension (30). The relative risk of hemorrhagic strokes is reported to be 1.2 for nonsmokers who used oral contraceptives. 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for non-smokers and 2.7 for users with severe hypertension (30). The attributable risk is greater in older women (2).

e) Atherosclerotic vascular diseases

Oral contraceptives have shown to increase both the relative and attributable risks of cardiovascular events (thrombotic and hemorrhagic strokes) although, in general, the risk is greatest among older (>35 years). Hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both types of strokes, and smoking was estimated to increase the risk of stroke (27-29).

In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for hemorrhagic strokes to 14 for users with severe hypertension (30). The relative risk of hemorrhagic strokes is reported to be 1.2 for nonsmokers who used oral contraceptives. 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for non-smokers and 2.7 for users with severe hypertension (30). The attributable risk is greater in older women (2).
in a large study, the relative risk of thrombotic strokes has been shown to range from 3 for non-users of oral contraceptives to 14 for users with severe hyperension (23). The relative risk of hemorrhagic strokes is reported to be 1.2 for non-users who used oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 3.6 for smokers who used oral contraceptives, 6.8 for non-smokers who used oral contraceptives, and 14.8 for non-smokers who used oral contraceptives with severe hypertension (23). The relative risk is also greater in older women (2).

5. Dose-related risk of vascular disease from oral contraceptives

A positive association has been observed between the amount of estrogen and progesterone in oral contraceptives and the risk of vascular disease (24,25). A decrease in serum high density lipoproteins (HDL) has been reported with many progestational agents (24-25). A decline in serum high density lipoproteins has been associated with an increased incidence of athero-sclerosis (25). Because estrogen increases HDL cholesterol, the net effect of an oral contraceptive depends on a balance between doses of estrogen and progesterone and the nature and amount of progestagens used in the contraceptives. The amounts of both hormones should be considered in the choice of an oral contraceptive.

Monitoring exposure to estrogen and progesterone is in keeping with good principles of pharmacology. For any particular estrogen/progesterone combination, the dosage regimen prescribed should be one which contains the least amount of estrogen and progesterone that is compatible with a low failure rate and the needs of the individual patient. New acceptance of oral contraceptives agents should be started on preparations containing 0.025 mg or less of estrogen.

6. Persistence of risk of vascular disease

There are two studies which have shown persistence of risk after cessation of use of oral contraceptives. In a study of the United States, the risk of developing myocardial infarction after discontinuation of oral contraceptives persisted for 1-2 years in women who stopped using oral contraceptives for five or more years, but the increased risk was not demonstrated in other age groups (26). In another study in Great Britain, the risk of developing cerebrovascular disease persisted for at least 6 years after discontinuation of oral contraceptives, although excess risk was very small (27). However, both studies were performed with oral contraceptives containing 0.05 mg or higher of estrogens.

2. ESTIMATES OF MORTALITY FROM CONTRACEPTIVE USE

One study gathered data from a variety of sources which have calculated the mortality rate associated with different methods of contraception at different ages (Table I). These estimates include the combined risk of death associated with contraceptive methods plus the risk attributable to pregnancy in the event of method failure. Each method of contraception has its specific benefits and risks.

The study concluded that the reduction in mortality for all contraceptive users 30 and older was 76 and 40 and older who did not smoke, mortality associated with all methods of birth control is low and below that associated with childbirth.

The observation of an increase in risk of mortality with age for oral contraceptive users (30), when compared with a woman who did not smoke, mortality associated with all methods of birth control is low and below that associated with childbirth.

Current clinical recommendation involves the use of lower estrogen formulations and a careful consideration of risk factors. In 1985, the Fertility and Maternal Health Group Advisory Committee was asked to review the use of oral contraceptives in women 40 years of age and over. The Committee concluded that although cardiovascular disease risk may be increased with oral contraceptives due to age 40 in healthy non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women and with the alternative surgical and medical procedures which may be necessary if such women do not have access to effective and acceptable means of contraception. The Committee recommended that the benefits of low-dose oral contraceptive use by healthy non-smoking women over 40 may outweigh the possible risks.

Of course, older women, all women who take oral contraceptives, should take an oral contraceptive which contains the least amount of estrogen and progesterones that is compatible with a low failure rate and individual patient needs. (See Table II.)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No fertility control method**</td>
<td>7.0</td>
<td>7.4</td>
<td>9.1</td>
<td>14.8</td>
<td>25.7</td>
<td>28.2</td>
<td></td>
</tr>
<tr>
<td>Oral contraceptives (non-smoker)***</td>
<td>0.5</td>
<td>0.3</td>
<td>0.9</td>
<td>1.9</td>
<td>3.8</td>
<td>3.6</td>
<td></td>
</tr>
<tr>
<td>Oral contraceptives smoker***</td>
<td>2.2</td>
<td>2.4</td>
<td>6.6</td>
<td>13.5</td>
<td>51.1</td>
<td>177.2</td>
<td></td>
</tr>
<tr>
<td>IUD**</td>
<td>0.8</td>
<td>0.8</td>
<td>1.0</td>
<td>1.4</td>
<td>1.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condom*</td>
<td>1.1</td>
<td>1.6</td>
<td>0.7</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Douching/proper hygiene***</td>
<td>1.9</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>2.2</td>
<td>2.9</td>
<td></td>
</tr>
<tr>
<td>Periodic abstinence***</td>
<td>2.3</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>2.9</td>
<td>3.6</td>
<td></td>
</tr>
</tbody>
</table>

* Deaths are from natural causes
** Deaths are from method-related deaths
*** Deaths are method-related

(Adapted from H.W. Ory, ref. 25)

3. CARCINOMA OF THE REPRODUCTIVE ORGANS AND BREASTS

Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian and cervical cancer in women using oral contraceptives. While there are conflicting reports, most studies suggest that the use of oral contraceptives is not associated with an overall increase in the risk of developing breast cancer. Some studies have reported an increased relative risk of developing breast cancer, particularly in younger age groups. This increased relative risk appears to be related in various sites case (26-43, 79-88).
Some studies suggest that oral contraceptive use has been associated with an increase in the risk of certain gastrointestinal problems in some populations of women (45-46). However, there is no conclusive evidence to support the risk in which such associations may be due to differences in sexual behavior and other factors.

4. HEPATIC NEOPLASIA

Benign hepatic adenomas are associated with oral contraceptive use, although the incidence of benign tumors is low in the United States. However, the presence of these tumors may increase the risk of developing liver cancer. The risk is increased in women with a history of oral contraception, higher dose (40), or use of oral contraceptives for longer periods of time (50, 51). The risk of developing liver cancer is greater in women who use oral contraceptives for longer than 5 years.

5. OCULAR LESIONS

There have been reports of retinal hemorrhages associated with the use of oral contraceptives. However, the overall risk is low. Proper medical evaluation and appropriate diagnostic tests should be undertaken immediately.

6. ORAL CONTRACEPTIVE USE BEFORE OR DURING EARLY PREGNANCY

Elevated serum prolactin levels have been reported in women who use oral contraceptives prior to pregnancy (56-57). The use of oral contraceptives during early pregnancy may also increase the risk of spontaneous abortion. For this reason, oral contraceptives should not be used during pregnancy to treat threatened or habitual abortion. The abortion should be confirmed by ultrasound or other appropriate diagnostic tests before continuing oral contraceptive use.

7. GALLBLADDER DISEASE

Liver function studies have reported an increased incidence of gallbladder surgery in women taking oral contraceptives. However, the overall risk is low. Women who use oral contraceptives may have an increased risk of developing gallbladder disease. The risk is increased in women who use oral contraceptives for longer periods of time.

8. CARBOHYDRATE AND LIPID METABOLIC EFFECTS

Oral contraceptives have been shown to increase the risk of developing type 2 diabetes mellitus and hyperinsulinemia. Women with a history of diabetes mellitus are at increased risk of developing oral contraceptive use. Women with a history of diabetes mellitus are at increased risk of developing oral contraceptive use. Women with a history of diabetes mellitus are at increased risk of developing oral contraceptive use. Women with a history of diabetes mellitus are at increased risk of developing oral contraceptive use.

9. ELEVATED BLOOD PRESSURE

An increase in blood pressure has been reported in women taking oral contraceptives (68). This increase is more likely to occur in older women (69) and in women taking oral contraceptives for longer periods of time. Women with a history of high blood pressure should be monitored closely. Women with a history of high blood pressure should be monitored closely. Women with a history of high blood pressure should be monitored closely.

10. HEADACHE

Women who use oral contraceptives may experience menstrual-like headaches. These headaches are usually mild and resolve within a few days. Women who use oral contraceptives may experience menstrual-like headaches. These headaches are usually mild and resolve within a few days. Women who use oral contraceptives may experience menstrual-like headaches. These headaches are usually mild and resolve within a few days.

11. BLEEDING IRREGULARITIES

Bleeding irregularities are common in women taking oral contraceptives. However, the overall risk is low. Women who use oral contraceptives may experience menstrual-like headaches. These headaches are usually mild and resolve within a few days. Women who use oral contraceptives may experience menstrual-like headaches. These headaches are usually mild and resolve within a few days.

12. ECZEMATIC PREGNANCY

Eczema as well as atopic dermatitis may occur during oral contraceptive use.

PRECAUTIONS

1. PHYSICAL EXAMINATION AND FOLLOW-UP

A good medical practice for all women who are at risk for serious illness or injury that may require oral contraceptive use, including women using oral contraceptives. The physical examination should be directed toward the detection of any abnormalities or other medical conditions that may require oral contraceptive use.

2. LIP DISORDERS

Women who are being treated for hyperlipidemia should be followed closely if they elect to use oral contraceptives. Women with hyperlipidemia may have a decreased risk of developing liver cancer.

3. LIVER FUNCTION

Women who have a history of liver disease or who are taking drugs that affect liver function should be monitored closely.

4. FLUID RETENTION

Women with a history of high blood pressure or who are taking diuretics should be monitored closely.

5. EMOTIONAL DISORDERS

Women with a history of depression should be monitored closely.

6. CONTACT LENSES

Women who use contact lenses should be monitored closely.
examinations, including women using oral contraceptives. The physical examination, however, may be deferred up to 2 weeks or more of oral contraceptives if requested by the woman and judged appropriate by the clinician. The physical examination should include breast palpation and any other relevant examination as indicated by the woman's past or present health status. If prolonged amenorrhea or the absence of menses is noted, pregnancy should be ruled out. If the woman is 1 year or more postmenopausal, the postmenopausal status should be confirmed by the absence of a menstrual bleed or a positive serum pregnancy test. If menstruation is not absent or if the woman is less than 1 year postmenopausal, a pregnancy test should be performed.

2. LIPID DISORDERS
Women who are being treated for hyperlipidemia should be followed closely if they are to be treated for hyperlipidemia. Some patients may develop elevated serum lipids and may require the concurrent use of hyperlipidemic agents.

3. LIVER FUNCTION
If the drug is used in any woman receiving such drugs, the medication should be stopped. Serum transaminases may be elevated in patients with impaired liver function.

4. FLUID RETENTION
Oral contraceptives may cause some degree of fluid retention. They should be discontinued with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention.

5. EMOTIONAL DISORDERS
Women with a history of depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

6. CONTACT LENSES
Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

7. DRUG INTERACTIONS
Reduced efficacy and increased evidence of breakthrough bleeding and menstrual irregularities have been associated with concurrent use of estrogens. A similar association, though less severe, has been reported with barbiturates, phenytoin, phenobarbital, carbamazepine and possibly with griseofulvin, ampicillin, and trimethoprim (sulfamethoxazole).

8. INTERACTIONS WITH LABORATORY TESTS
Certain endocrine and liver function tests and blood components may be affected by oral contraceptives.

9. PREGNANCY
See WARNINGS section.

10. BREAST FEEDING
Pregnancy Category X. See CONTRAINDICATIONS and WARNINGS sections.

11. NURSING MOTHERS
Smaller amounts of oral contraceptives are excreted in the milk of nursing mothers and a low adverse effect on the child has been reported, including jaundice and breast enlargement. In addition, oral contraceptives given in the puerperal period may interfere with lactation by decreasing the quantity and quality of breast milk. If possible, the nursing mother should be advised not to use oral contraceptives but to use other forms of contraception until she has completely weaned her child.

12. SEXUALLY TRANSMITTED DISEASES
Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

INFORMATION FOR THE PATIENT
See Parent Labeling Printed Below

ADVERSE REACTIONS
An expected risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS section):

- Thromboembolism, venous thromboembolism with or without embolism
- Arterial thromboembolism
- Premature menopause
- Myocardial infarction
- Cerebral hemorrhage
- Cerebral thrombosis
- Hepatotoxicity
- Gallbladder disease
- Hepatic adhesions or biliary tract tumors

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug-related:

- Nausea
- Vomiting
- Gastrointestinal symptoms (such as abdominal cramps and bloating)
- Breast tenderness
- Spotting
- Change in menstrual flow
- Amenorrhea
- Temporary infertility after discontinuation of treatment
Edema
Weighing changes, lassitude, enlargement, sensibility
Change in weight (increase or decrease)
Change in cervical exudate and sensation
Diminution in sensation when given immediately postpartum
Liver function
Magnesium
Rhinorrhea
Tinnitus
Loss of scalp hair
Endometriosis
Eye symptoms
Nervousness
Depression
Flushing
Jasmin
Loss of vision
Nausea
Obesity
Increased frequency of micturition
Increased sensibility of psychic phenomena
Increased sensibility of vaginal discharge
Excessive menstruation
Irregular vaginal function
Hypothyroidism
Diabetes mellitus
Acne
Changes in hair
Diarhoea
Budd-Chiari Syndrome

OVERDOSE
Serious side effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdose may cause nausea, and withdrawal bleeding may occur in females.

NON-CONTRACEPTIVE HEALTH BENEFITS
The following non-contraceptive health benefits related to the use of oral contraceptives are supported by epidemiological studies on which these products have an advantage in the prevention of adverse outcomes associated with hormone replacement therapy: decreasing breast cancer incidence.

BENEFITS TO THE USER
The benefits of oral contraceptives for the user include:

1. Decrease in the incidence of ectopic pregnancy
2. Decrease in the incidence of benign breast disease
3. Decrease in the incidence of ovarian cancer
4. Decrease in the incidence of uterine cancer
5. Decrease in the incidence of endometrial cancer
6. Decrease in the incidence of ovarian cancer

DOSE AND ADMINISTRATION
To achieve maximum contraceptive effectiveness, desogestrel and ethinyl estradiol tablets must be taken exactly as directed and at intervals not exceeding 24 hours. The tablets are taken once a day for 21 days followed by 7 days with no tablets taken. This regimen is repeated with the same tablets every month. During the first seven days of the cycle, the patient should take the tablet every day to ensure maximum protection against pregnancy. It is important to remember that the tablet contains no hormones and is therefore not necessary to use a contraceptive method during this period.

21-Day Regimen (Day 1 Start)
The dosage of Desogestrel and Ethinyl Estradiol Tablet 21-Day Regimen is as follows: 1 tablet is taken daily for the first 21 days of the menstrual cycle. On the 22nd day, the patient should stop taking the tablets and begin a new pack on the 23rd day. The dosage regimen then continues with 7 days of no medication, followed by 21 days of medication, instituting a three-weeks-on, one-week-off dosage regimen.

21-Day Regimen (First Day Start)
When taking the Desogestrel and Ethinyl Estradiol Tablet 21-Day Regimen, the first tablet should be taken on the first day of the menstrual cycle. If the tablet is taken on the first day of the menstrual cycle, the patient should continue to take one tablet daily until the 21st day, when the second tablet is taken. The dosage regimen then continues with 7 days of no medication, followed by 21 days of medication, instituting a three-weeks-on, one-week-off dosage regimen.

CONTRAINDICATIONS
The use of Desogestrel and Ethinyl Estradiol Tablet 21-Day Regimen in pregnancy may be associated with an increased risk of thromboembolic disease. The use of these products is not recommended for women who are pregnant or lactating. Women who are breastfeeding should not use these products. Women who are breastfeeding should use an alternative contraceptive method during the postpartum period until they have been given a minimum of 4 weeks of medication. See also CONTRAINDICATIONS and WARNINGS concerning thromboembolic disease.
The patient should be instructed to use a back-up method of birth control if she has sex in the seven (7) days after missing pills.

28-Day Regimen (Day 1 Start)

The dosage of Desogestrel and Ethinyl Estradiol Tablets 28-Day Regimen for the initial cycle of therapy is one tablet administered daily from the 1st day through 21st day of the menstrual cycle, counting the first day of menses as "Day 1." Tablets are taken without interruption as follows: One rose-colored tablet daily for 21 days, then one white tablet daily for 7 days. After 28 tablets have been taken, a new course is started and a rose-colored tablet is taken the next day.

The use of the Desogestrel and Ethinyl Estradiol Tablet 28-Day Regimen for contraception may be initiated 4 weeks postpartum in women who elect not to breast feed. When the tablets are administered during the postpartum period, the increased risk of thromboembolic disease associated with the postpartum period must be considered. (See CONTRAINDICATIONS and WARNINGS concerning thromboembolic disease. See also PRECAUTIONS for "Nursing Mothers.") If the patient starts on desogestrel and ethinyl estradiol tablets postpartum, and has not yet had a period, she should be instructed to use another method of contraception until a rose-colored tablet has been taken daily for 7 days. The possibility of ovulation and conception prior to initiation of medication should be considered. If the patient misses one (1) active tablet in Weeks 1, 2, or 3, the tablet should be taken as soon as she remembers. If the patient misses two (2) active tablets in Week 1 or Week 2, the patient should take two (2) tablets the day she remembers and then (2) tablets the next day, and then continue taking one (1) tablet a day until the 21st day. The patient should be instructed to use a back-up method of birth control if she has sex in the seven (7) days after missing pills.

28-Day Regimen (Day 1 Start)

When using the Desogestrel and Ethinyl Estradiol Tablet 28-Day Regimen, the first rose-colored tablet should be taken on the first Sunday after menstruation begins. If period begins on Sunday, the first rose-colored tablet is taken on that day. If switching from another oral contraceptive, the first rose-colored tablet should be taken on the first Sunday after the last active tablet of the previous product. Tablets are taken without interruption as follows: One rose-colored tablet daily for 21 days, then one white tablet daily for 7 days. After 28 tablets have been taken, a new course is started and a rose-colored tablet is taken the next day. If the patient misses two (2) tablets in the three weeks or misses three (3) or more active tablets in a row, the patient should throw out the rest of the pack and start a new pack that same day. The patient should be instructed to use a back-up method of birth control if she has sex in the seven (7) days after missing pills.
days after missing pill. If the patient missed two (2) active tablets in one past week or three (3) or more tablets in a new week, the patient should continue using one tablet every day until Sunday. On Monday, the patient should start over the rest of the pack and start a new pack that same day. The patient should not resume the back-up-back-up method of birth control if she has sex in the seven (7) days after missing pills.

ALL ORAL CONTRACEPTIVES

A prospective study of funding, and amenorrhea are frequent reasons for failure and continuation of oral contraceptives. In breakthrough bleeding, in all cases of breakthrough bleeding from the vagina, nonsteroidal (nonsteroidal) contraceptives should be used as in individual patients perceiving oral contraceptive bleeding from the vagina, adequate contraceptive measures are established to rule out pregnancy or menstruation. If amenorrhea has occurred, if a change to a different formulation may lower the reliability of oral contraceptives with a higher estrogen content, when potentially useful in minimizing menstrual irregularity, should be done only if necessary since this may increase the risk of thromboembolism or stroke.

Use of oral contraceptives in the event of a missed period:

1. If the patient was not adherent to the prescribed schedule, the possibility of pregnancy should be considered at the time of the first missed period and oral contraceptive use should be discontinued until pregnancy is ruled out.

2. If the patient has had abnormal bleeding in the past, or in two consecutive periods, pregnancy should be ruled out before continuing oral contraceptive use.

HOW SUPPLIED

Dosingage and Ethynyl Estradiol Tablets 28 Day Regimen blister cards contain 21 round, uncoated, rose-colored tablets and 7 round, uncoated white tablets. Each rose-colored tablet (dosed with "A" on one side and "A21" on the other side) contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol. Each white tablet (dosed with "B" on one side and "B21" on the other side) contains inert ingredients.

Cartons of 6 blister cards NDC 73069-876-28

Dosingage and Ethynyl Estradiol Tablets 28 Day Regimen blister cards contain 21 round, uncoated rose-colored tablets. Each rose-colored tablet (dosed with "A" on one side and "A21" on the other side) contains 0.15 mg desogestrel and 0.03 mg ethinyl estradiol.

Cartons of 6 blister cards NDC 71855-575-21

STORAGE: Store at controlled room temperature 15°-30°C (59°-86°F).

It is only.

BURNHAM PHARMACEUTICALS, INC.
CINCINNATI, OHIO 45219 USA

REFERENCES

Brief Summary Patient Package Insert
Desogestrel and Ethinyl Estradiol Tablets

Body

Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy, and when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of large numbers of pill users is less than 1% per year when women who miss pills are included. For most women, oral contraceptives are also free of serious or unpleasant side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, or high cholesterol
- have had clotting disorders, heart attack, stroke, angina pectoris, cancer of the breast or other organ, paucity or malnutrition, or benign liver tumors
- although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer low-dose contraceptives), there are also greater potential health risks associated with pregnancy in older women.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Cigarette smoking increases the risk of various cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite substantial in women over 30 years of age. Women who use oral contraceptives are strongly advised not to smoke.

Most side effects of the pill are not serious. The most common effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, headache, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use.

The serious side effects of the pill occur very rarely, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with oral contraceptive use:

1. Blood clots in the legs (thrombophlebitis) or lungs (pulmonary embolism), stoppage of urine, or rupture of a blood vessel in the brain (cerebral hemorrhage), or bleeding from the nose or mouth, or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes, and substantially serious medical consequences.

2. Live tumors, which may rupture or cause severe bleeding. A postpartum or not due to an obstruction has been found with the pill and liver cancer. However, there can be no evidence that the chance of developing liver cancer from using the pill is as great as other cancers.

3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed patient labeling given to you by your supplier or clinic. If you notice any unusual physical disturbances while taking the pill, in addition, drugs such as diuretics, as well as some antidepressants and some antibiotics may increase oral contraceptive effectiveness.

There is conflict among studies regarding breast cancer and oral contraceptive use. Some studies have reported no increased risk of developing breast cancer, particularly in a younger age. This increased risk appears to be related to duration of use. The purpose of the studies has not been to establish a greater risk in the risk of developing breast cancer. Some studies have found an increase in the incidence of cancer in women who use oral contraceptives; however, this finding may be related to factors other than the use of oral contraceptives. There is insufficient evidence to rule out the possibility that this may cause some cancers.

Talk to the pill provides some important non-contraceptive benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and lining of the uterus.

Be sure to discuss any medical condition you may have with your doctor or clinic. Your doctor or clinic will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be repeated in another time if you request it and your doctor or clinic believes that it is a good medical practice to do so. It should be rechecked at least once a year when taking oral contraceptives. The detailed patient information sheet that you further information which you should read and discuss with your doctor or clinic.

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV/AIDS and other sexually transmitted diseases such as chlamydia, genital herpes, gonorrhea, hepatitis B, and syphilis. 
Detailed Patient Labeling

Please Note: This labeling is revised from time to time as important new medical information becomes available. Therefore, please review this labeling carefully.

The following oral contraceptives contain a combination of progestogen and estrogen, the two kinds of female hormones:

Dempsey and Ethinyl Estradiol Tablet 21 Day Regimen Blister Card
Each rose-colored tablet contains 0.15 mg demepoxy and 0.03 mg ethinyl estradiol.

Dempsey and Ethinyl Estradiol Tablet 21 Day Regimen Blister Card
Each white tablet contains 0.15 mg demepoxy and 0.03 mg ethinyl estradiol.

Introduction

Any woman who considers using oral contraceptives (the birth control pill or the pill) should understand the benefits and risks of using this form of birth control. This patient labeling will give you much of the information you will need to make this decision and will also help you determine if you are at risk of developing any of the typical side effects of the pill. It will tell you how to use the pill properly so that it will be as effective as possible. However, this labeling is not a substitute for a careful discussion between you and your doctor or clinic. You should discuss the information provided in this labeling with him or her, both when you first start taking the pill and during your visits. You should also follow your doctor’s or clinic’s advice with regard to regular check-ups even if you are on the pill.

Effectiveness of oral contraceptives

Oral contraceptives, or "pill blockers," as the pill is called, is used to prevent pregnancy. It is more effective than any other non-surgical methods of birth control. When they are taken correctly, the chance of becoming pregnant is less than 1% per year. Women who use oral contraceptives have a lower incidence of ovarian cysts, benign breast problems, and endometrial carcinoma. In addition, use of oral contraceptives is associated with a decreased risk of ovarian and uterine cancer.

Who should not take oral contraceptives

Some women should not use the pill. For example, you should not take the pill if you are pregnant or think you may be pregnant. You should also not use the pill if you have any of the following conditions.

A history of heart attack or stroke

Blood clots in the veins (thrombophlebitis) or the lungs (pulmonary embolism), or eye

A history of blood clots in the deep veins of your legs

Chronic pain (angina pectoris)

Known or suspected breast cancer or cancer of the uterus, cervix, or vagina

Unexplained vaginal bleeding until a diagnosis is reached by your doctor)

Yellowing of the skin or the eyes (jaundice) during pregnancy or during previous use of the pill

Liver tumor (benign or cancerous)

Known or suspected pregnancy

Tell your doctor or clinic if you have ever had any of these conditions. Your doctor or clinic can recommend a safer method of birth control.

Other considerations before taking oral contraceptives

Tell your doctor or clinic if you want or need to:

Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram

Depression

Elevated cholesterol or triglycerides

High blood pressure

Migraine or other headaches or epilepsy

Mental depression

Cataracts, heart or kidney disease

History of severe or irregular menstrual periods

Women with any of these conditions should be checked often by your doctor or clinic if they choose to use oral contraceptives.

Also, be sure to inform your doctor or clinic if you smoke or are on any medications.

Risks of taking oral contraceptives

1. Risk of developing blood clots

Blood clots and blockage of blood vessels are one of the most serious side effects of taking oral contraceptives and can cause death or serious disability. In particular, a clot in one of the legs or the lungs can cause death or severe disability. Women with any of these conditions should not be on oral contraceptives.

Also, be sure to inform your doctor or clinic if you smoke or are on any medications.
greater with desensitized-curing oral contraceptives, such as dienogest and ethinylestradiol, than with other low-dose pills. Rarely, oral contraceptives may cause bleeding or spotting between periods. If you have breakthrough bleeding or spotting, you should consult your doctor or clinic about stopping oral contraceptives three to four weeks before surgery and not taking oral contraceptives for two weeks after surgery or during rest test. You should also not take oral contraceptives soon after delivery of a baby. It is advisable to wait for at least four weeks after delivery if you are not breast feeding or four weeks after a second trimester abortion. If you are breast feeding, you should wait until you have weaned your child (before using the pill. (See also the section on Breast Feeding in General Precautions.)

The risk of cardiovascular disease in oral contraceptive users may be higher in users of high-dose pills and may be greater with longer duration of oral contraceptive use. In addition some of these increased risks may continue for a number of years after stopping oral contraceptives. The risk of abnormal breast cancer increases with age in both users and nonusers of oral contraceptives, but the increased risk from the oral contraceptive appears to be present at all ages. For women aged 25 to 44 in a population of 1 in 2,000 using oral contraceptives will be hospitalized each year because of abnormal bleeding. Among nonusers in the same age group, about 1 in 20,000 would be hospitalized each year. For oral contraceptive users in general, it has been estimated that in women between the ages of 35 and 54, the risk of death due to a coronary disorder is about 1 in 12,000 per year, whereas for nonusers the risk is about 1 in 50,000 per year. In the age group 35 to 44, the risk is estimated to be about 1 in 20,000 per year for oral contraceptive users and about 1 in 10,000 per year for nonusers.

2. Breast disease and breast cancer

Oral contraceptives may increase the tendency to develop stroke (sudden or rapid onset of weakness on one side of the body) and angina (sudden onset of pain in the chest). Any of these conditions can cause death or serious disability. Smoking greatly increases the possibility of suffering heart attacks and strokes. Furthermore, smoking and the use of oral contraceptives greatly increase the chances of developing and dying of heart disease.

3. Gallbladder disease

Oral contraceptive users probably have a greater risk than nonusers of having gallbladder disease, although this risk may be related to pills containing high doses of estrogen.

4. Liver tumors

In rare cases, oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not verified association has been found with the pill and liver cancer in two studies, in which a few women who developed these very rare cancers were found to have used oral contraceptives for long periods. However, liver cancers are rare.

5. Cancer of the reproductive organs and breast

There is concern among studies regarding breast cancer and oral contraceptive use. Some studies have reported an increase in the risk of developing breast cancer, particularly at a younger age. The increased risk appears to be related to duration of use. The majority of studies have found no overall increase in the risk of developing breast cancer. The few studies that found an increased risk were for women who used oral contraceptives for many years and were associated with certain types of oral contraceptives. All women who have used oral contraceptives have a slightly increased risk of developing breast cancer. There is insufficient evidence to rule out the possibility that pills may cause such cancers.

ESTIMATED RISK OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY

All methods of birth control and pregnancy are associated with a risk of developing certain diseases which may lead to disability or death. An estimate of the number of deaths associated with different methods of birth control and pregnancy has been calculated and is shown in the following table.

<table>
<thead>
<tr>
<th>Method of control and sex ratio</th>
<th>15-19</th>
<th>20-24</th>
<th>25-29</th>
<th>30-34</th>
<th>35-39</th>
<th>40-44</th>
</tr>
</thead>
<tbody>
<tr>
<td>No method control method</td>
<td>2.4</td>
<td>3.3</td>
<td>4.1</td>
<td>4.9</td>
<td>5.8</td>
<td>7.1</td>
</tr>
<tr>
<td>Oral contraceptives non-smoker</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
<td>0.7</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Oral contraceptives smoker</td>
<td>2.2</td>
<td>3.3</td>
<td>4.4</td>
<td>5.5</td>
<td>6.6</td>
<td>7.7</td>
</tr>
<tr>
<td>IUD</td>
<td>0.8</td>
<td>0.9</td>
<td>1.0</td>
<td>1.1</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Condom</td>
<td>1.1</td>
<td>1.3</td>
<td>1.5</td>
<td>1.7</td>
<td>1.9</td>
<td>2.1</td>
</tr>
<tr>
<td>Diaphragm/sterilization</td>
<td>1.9</td>
<td>2.1</td>
<td>2.3</td>
<td>2.5</td>
<td>2.7</td>
<td>2.9</td>
</tr>
<tr>
<td>Contraceptive abortion</td>
<td>2.5</td>
<td>2.8</td>
<td>3.1</td>
<td>3.2</td>
<td>3.4</td>
<td>3.6</td>
</tr>
</tbody>
</table>

- Deaths are birth related
- Deaths are method related

In the preceding table, the risk of death from any birth control method or less than the risk of childbirth, except for oral contraceptive users of the age of 35 who smoke and use users over the age of 35 but even if they do not smoke. It can be seen at the table that for women aged 15 to 19, the risk of death was highest with pregnancy (7-28 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death was lowest than that associated with smoking for any age group. Although the women aged 35, the estimated number of deaths exceeds those for other methods of birth control. It is a woman who is age 40 and smokers. Her estimated risk of death is four times higher (117:100,000 women) than the estimated number associated with pregnancy (28:100,000 women) in that age group. The suggestion that women over 40 who do not smoke should not take oral contraceptives is based on estimates from other, higher-dose pills. An Advisory Committee of the FDA discussed this issue in 1988 and recommended that the benefits of low-dose oral contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks.

WARNING SIGNS

If any of these adverse effects occur while you are taking oral contraceptives, call your doctor or clinic immediately:
- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible case in the lung)
- Pain in the calf (indicating a possible clot in the leg)
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack)
- Sudden severe headache or vomiting, dizziness or feeling, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke)
- Sudden partial or complete loss of vision (indicating a possible clot in the brain)
- Breast lumps (indicating possible breast cancer or a fibrocystic disease of the breast ask your doctor or clinic to show you how to examine your breasts)
- Soreness or tenderness in the stomach area (indicating a possibly ruptured liver)
- Difficulty in breathing, weakness, loss of energy, fatigue, or change in mood (possibly indicating liver problems)
- Jaundice or a yellowing of the skin or eyes, accompanied by liver, fatigue, loss of appetite, dark colored urine, or light colored bowel movements (indicating possible liver problems)
WARNING SIGNALS
If any of these adverse effects occur while you are taking oral contraceptives, call your doctor or clinic immediately:
• Sharp pain, cramping, or sudden loss of breath (indicating a possible clot in the lung)
• Pain in the calf (indicating a possible clot in the leg)
• Crushing chest pain or tightness in the chest (indicating a possible heart attack)
• Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or balance, weakness or dizziness in an arm or leg, sudden itching, skin rash, severe swelling of the face, chest, or tongue
• Sudden partial or complete loss of vision (indicating a possible clot in the eye)
• Bruise easily (indicating possible bruising or INTERNAL BLEEDING). If the bruises increase, tell your doctor or clinic. You may have to stop taking your pills for a while. In time, bruising may be improved and usually does not indicate any serious problems. It is important to continue taking your pills on schedule. If bleeding occurs in more than one cycle or lasts for more than a few days, talk to your doctor or clinic.
• Swelling of the face, chest, or tongue
• Difficulty in swallowing, weakness, loss of energy, fatigue, or change in mood (possibly indicating depression)
• Blurriness or yellowing of the skin or eyes, accompanied frequently by fever, tongue, loss of appetite, dark colored urine, or short colored brown movements (indicating possible liver problems)

SIDE EFFECTS OF ORAL CONTRACEPTIVES
1. Menstrual bleeding
Irregular vaginal bleeding or spotting may occur while you are taking the pill. Irregular bleeding may vary from slight spotting between menstrual periods to breakthrough bleeding which is a very much like a regular period. Irregular bleeding occurs more often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for a year. Such changes may be temporary and usually do not indicate any serious problems. It is important to continue taking your pills on schedule. If bleeding occurs in more than one cycle or lasts for more than a few days, talk to your doctor or clinic.
2. Contact lenses
If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or clinic.
3. Fluid retention
Oral contraceptives may cause edema (fluid retention) with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your doctor or clinic.
4. Migraines
A sudden swelling of the skin or a possible, particularly of the face, which may occur
5. Other side effects
Other side effects may include nausea and vomiting, change in appetite, headaches, nervousness, depression, breast tenderness, breast lump, nausea, and weight fluctuations.
If any of these side effects bother you, call your doctor or clinic.

GENERAL PRECAUTIONS
1. Missed periods and use of oral contraceptives before starting new prophyllactics
There may be some times when you may not menstruate regularly after you have completed taking a cycle of pills. If you have taken your pill regularly and miss one menstrual period, continue taking your pills for the next cycle. Be sure to inform your doctor or clinic before doing so. If you have not taken the pill as instructed and missed a menstrual period, you may be pregnant. If you missed two consecutive menstrual periods, you may be pregnant. Check with your doctor or clinic immediately to determine whether you are pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant, but continue to use another method of contraception.

There is no conclusive evidence that oral contraceptives are associated with an increase in certain defects, which may have occurred during early pregnancy. However, a few studies have reported that oral contraceptives may be associated with birth defects. However, these findings have not been borne out in more recent studies. Nevertheless, oral contraceptives or any other drugs should not be used during pregnancy unless clearly necessary and prescribed by your doctor or clinic. You should check with your doctor or clinic about risks to your unborn child at any medication taken during pregnancy.
2. While breast feeding
If you are breast feeding, consult your doctor or clinic before starting oral contraceptives. Some of the drugs will be passed on to the child or the milk. A few adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. In addition, oral contraceptives may decrease the amount and quality of your milk. It is possible to use oral contraceptives while breast feeding. You should consult with your doctor and child about risks to your unborn child at any medication taken during pregnancy.

3. Laboratory tests
If you are scheduled for any laboratory tests, tell your doctor or clinic you are taking birth control pills. Certain blood tests may be affected by birth control pills.
4. Drug interactions
Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include antibiotics, drugs used for epilepsy such as Dilantin, and phenothiazines such as Thorazine and Stelazine. You may need to use additional contraception when you take these drugs which can make oral contraceptives less effective.

5. Sexually transmitted diseases
This product (oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

HOW TO TAKE THE PILL
IMPORTANT POINTS TO REMEMBER BEFORE YOU START TAKING YOUR PILLS:
1. BE SURE TO READ THESE DIRECTIONS. Before you start taking your pills.
2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. If you miss pills you could get pregnant. This includes starting the exact time. The more pills you miss, the more likely you are to get pregnant.
3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your doctor or clinic.
4. MISSED PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up those missed pills. On the days you take 2 pills to make up for missed pills, you should also have a little sick to your stomach.
5. IF YOU HAVE VOMITING OR DIARRHEA, FOR ANY REASON, OR IF YOU TAKE SOME MEDICINES, including some antibiotics, your pills may not work as well. Use a back-up method such as condoms, foam, or spermicidal jellies until you check with your doctor or clinic.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic about how to make pill-taking easier or about using another method of birth control.
BEFORE YOU START TAKING YOUR PILLS:
1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. IT IS IMPORTANT TO TAKE IT AT ABOUT THE SAME TIME EVERY DAY.
2. LOOK AT YOUR PILL PACK TO SEE IF IT HAS 21 OR 26 PILLS:
   a. The 21-pill pack has 21 "active" (rose-colored) pills (with hormones) to take for 3 weeks, followed by 1 week without pills.
   b. The 28-pill pack has 21 "active" (rose-colored) pills (with hormones) to take for 3 weeks, followed by 1 week of "withdrawal" (white) pills (without hormones).
3. ALSO REMEMBER:
   a. where on the pack to start taking the pills.
   b. in what order to take the pills (follow the arrows).
   c. the week numbers printed on the pack.

### 28 Pill Pack

<table>
<thead>
<tr>
<th>Rose-colored tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>White tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

### 4. BE SURE YOU HAVE READY AT ALL TIMES:
   - ANOTHER KIND OF BIRTH CONTROL, such as condoms, foams, or sponges to use as a back-up in case you miss pills.
   - AN EXTRA FULL PILL PACK.

### WHEN TO START THE FIRST PACK OF PILLS:
- You have a choice of which day to start taking your first pack of pills. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.

**DAY 1 START:**
1. Peel the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is midnight when the bleeding begins).
2. Place this day label strip on the cycle label dispenser over the area that has the days of the week (starting with Sunday) printed on the blister card.

### Pick Correct Day Label

<table>
<thead>
<tr>
<th>Example Only:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Note: If the first day of your period is on a Sunday, you can also start on Day 7.

3. Take the first "active" (rose-colored) pill of the first pack during the first 24 hours of your period.

4. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

### SUNDAY START:
- Take the first "active" (rose-colored) pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
- Use another method of birth control as a back-up method if you have sex any time from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foams, or the sponge are good back-up methods of birth control.

### WHAT TO DO DURING THE MONTH:
1. **Take one pill at the same time every day until the pack is empty.** Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).
2. **Do not stop pills even if you do not have sex very often.**

### WHEN YOU FINISH A PACK OR Switch Your Brand of PILLS:
- **10 pills:** Wait 7 days to start the next pack. You will probably have your period during that week. Be sure that no more than 7 days pass between 21-day packs.
- **14 pills:** Start the next pack on the day after your last "reminder" pill. Do not wait any days between packs.

### WHAT TO DO IF YOU MISS PILLS:
- **If you missed 1 (rose-colored) "active" pill:**
  1. Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
  2. You do not need to use a back-up birth control method if you have sex. If you missed 2 (rose-colored) "active" pills in a row in WEEK 1 OR WEEK 2 of your pack:
    1. Take 2 pills on the day you remember and 2 pills the next day.
    2. Then take 1 pill a day until you finish the pack.
    3. You MAY BECOME PREGNANT if you have sex in the 2 days after you miss pills. You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for these 7 days.

### IF YOU MISS 2 (rose-colored) "active" pills in a row in WEEK 2 or WEEK 3:
1. **If you are a Day 1 Starter:** THROW OUT the rest of the pill pack and start a new pack that same day.
2. **If you are a Sunday Starter:**
   - Keep taking 1 pill every day until Sunday.
   - On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
   - You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
3. **If you miss 3 or more (rose-colored) "active" pills in a row (during the first 3 weeks):**
   - **If you are a Day 1 Starter:** THROW OUT the rest of the pill pack and start a new pack that same day.
   - **If you are a Sunday Starter:**
     - Keep taking 1 pill every day until Sunday.
     - On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
If you are a Sunday Starter:
Keep taking 1 pill every day until Sunday.
On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

2. You may not have your period this month but this is expected. If you miss
your period 2 months in a row, call your doctor or clinic because you might be preg-

3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
YOU MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for these 7 days.

4. If you have a 7-day break:
If you use a Sunday Starter,
Throw out the rest of the pack and start a new pack that same day.

5. If you use a Sunday Starter:
Keep taking 1 pill every day until Sunday.
On Sunday, THROW OUT the rest of the pack and start a new pack that same day.

6. You may not have your period this month but this is expected. If you miss
your period 2 months in a row, call your doctor or clinic because you might be preg-

7. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.
YOU MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for these 7 days.

A REMINDER FOR THOSE ON 21-DAY PACKS:
If you forget any of the 7 (white) "reminder" pills in Week 4,
Throw away the pack you missed
Keep taking 1 pill each day until the pack is empty.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE
MISSED,
Use a BACK-UP METHOD anytime you have sex,
KEEP TAKING ONE (one-color) "ACTIVE" PILL EACH DAY until you can reach your doctor or clinic.

PREGNANCY DUE TO PILLS:
Failure due to pills failure resulting in pregnancy is approximately one percent (i.e., one pregnancy per 100 women per year) if taken every day as directed, but more typical fail-
ure rates are about 3%. If failure occurs, the risk to the fetus is minimal.

PREGNANCY AFTER STOPPING THE PILLS:
There may not be any delays in becoming pregnant after you stop taking oral contracep-
tives, especially if you have irregular menstrual cycles before you used oral contracep-
tives. It may be advisable to postpone conception until you have menstruated regular-
ly once you have stopped taking the pills and desire pregnancy.

OVERDOSE:
Serious ill effects have not been reported following ingestion of large doses of oral contracep-
tives by young children. Overdose may cause nausea and withdrawal bleeding in females. In case of overdose, contact your doctor or clinic immediately.

OTHER INFORMATION:
Your doctor or clinic will give you a medical and family history before prescribing oral contracep-
tives and may examine you. The physical examination may be delayed to another
visit if you request it or your doctor or clinic believes that it is a good medical practice
on your doctor or clinic if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your doctor or clinic because this is a
time to determine if there are early signs of side effects of oral contraceptive use.

Do not use the drug for any condition other than the one for which it was prescribed.
This drug has been prescribed specifically for you; do not give it to others who may need
birth control pills.

HEALTH BENEFITS FROM ORAL CONTRACEPTIVES:
In addition to preventing pregnancy, use of contraception oral contraceptives may pro-
vide certain benefits. They are:
- menstrual cycles may become more regular
- blood flow during menstruation may be lighter and less iron may be lost.
- anemia due to iron deficiency is less likely to occur.
- pain or other symptoms during menstruation may be encountered less frequently.
- ectopic (tubal) pregnancy may occur less frequently.
- noncancerous cysts or lumps in the breast may occur less frequently.
- acne problems may occur less frequently.
- oral contraceptives may provide some protection against developing two forms of cancer: ovarian and breast cancer during the time of the uterus.

If you want more information about birth control pills, see your doctor, clinic or phar-
macist. They have a more technical booklet called the Professional Labeling, which you
may wish to read. The Professional Labeling is also published in the book entitled
Physicians' Desk Reference, available in many book stores and public libraries.

DUANEread PHARMACEUTICALS, INC.
CINCINNATI, OHIO 45223 USA

102550| 15. 04.69