Low-Ogestrel® 21 (noregesterone and ethinyl estradiol tablets USP: 0.3 mg/0.03 mg)
Low-Ogestrel® 28 (noregesterone and ethinyl estradiol tablets USP: 0.3 mg/0.03 mg)

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

ORAL CONTRACEPTIVE AGENTS

DESCRIPTION

Low-Ogestrel® 21 tablets (noregesterone and ethinyl estradiol tablets USP: 0.3 mg/0.03 mg) provide an oral contraceptive regimen containing 21 tablets. Each white, film-coated tablet contains 0.3 mg of noregesterone and 0.03 mg of ethinyl estradiol and the following inactive ingredients: microcrystalline cellulose, lactose, magnesium stearate, and yellowelope.

Low-Ogestrel® 28 tablets (noregesterone and ethinyl estradiol tablets USP: 0.3 mg/0.03 mg) provide an oral contraceptive regimen containing 28 tablets. Each white, film-coated tablet contains 0.3 mg of noregesterone and 0.03 mg of ethinyl estradiol and the following inactive ingredients: microcrystalline cellulose, lactose, magnesium stearate, and yellowelope.

The tablet contains a yellow luteinizing hormone-releasing hormone analog, which is a synthetic progestin and a weak estrogen. It is used to help regulate ovulation and prevent pregnancy.

CLINICAL PHARMACOLOGY

Combination oral contraceptives act by suppression of ovulation. Although the primary mechanism of this action is inhibition of ovulation, other changes include changes in the cervical mucus and changes in the endometrium.

INDICATIONS AND USAGE

Low-Ogestrel® noregesterone and ethinyl estradiol tablets USP: 0.3 mg/0.03 mg are indicated for the prevention of pregnancy in women who wish to use this product as a method of contraception.

The effectiveness of combination oral contraceptives is dependent upon continuous daily administration throughout the menstrual cycle. The first seven tablets contain a combination of 21 tablets, which contain the active ingredients, ethinyl estradiol and noregesterone. The seventh tablet contains only noregesterone and is a placebo.

CONTRAINDICATIONS

Oral contraceptives should not be used in women who have the following conditions:

- A past history of severe anemia or thromboembolic disease.
- Congestive heart failure.
- Plastic surgery or other major surgery involving the uterus.
- Known or suspected pregnancy.
- Known or suspected lactation.
- Known or suspected hepatic disease.
- Known or suspected allergy to progestins or estrogens.
- Known or suspected porphyrria.
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2. LIPID DISORDERS
Women who are being treated for hypercholesterolemia should be told that cholestyramine is used to treat hypercholesterolemia. Some women may experience loose stools and increased flatus. These side effects may be minimized by taking the drug with food or milk.

3. LIVER FUNCTION
If purpura develops in a woman receiving oral contraceptives, the medication should be discontinued. Severe hematomas may be poorly metastasized in women with impaired liver function.

4. FLUSHING IRRITABILITY
Oral contraceptives may cause some degree of fluid retention. They should be prescribed with caution in obese women or those with edema. Such symptoms may be aggravated by salt restriction.

5. EMOTIONAL DISORDERS
Women with a history of depression should be carefully observed and the drug discontinued if depression worsens.

6. CONTACT LENSES
Certain medical and drug treatment may lead to visual changes or changes in lens toleration may be assessed by an ophthalmologist.

7. DRUG INTERACTIONS
Reduced efficacy and increased incidence of loose stools and menstrual irregularities have been associated with concurrent administration of oral contraceptives and the following drugs: 
- Antihistamines
- Phenothiazines
- Reserpine
- Lithium
- Corticosteroids
- Phenylbutazone
- Oral anticoagulants
- Thiazide diuretics
- Certain antibiotics

8. INTERACTIONS WITH LABORATORY TESTS
The following drugs and their function may be affected by oral contraceptives:
- Glucocorticosteroids
- Anticoagulants
- Antihypertensives
- Thyroid hormones
- Oral anticoagulants
- Phenothiazines

9. BREAST CANCER
The following drugs and their function may be affected by oral contraceptives:
- Glucocorticosteroids
- Anticoagulants
- Antihypertensives
- Thyroid hormones
- Oral anticoagulants
- Phenothiazines

10. BIOMEDICAL
See WARNINGS section.

11. PREGNANCY
See CONTRAINDICATIONS and WARNINGS section.

12. NURSING MOTHERS
Small amounts of oral contraceptive steroids may be identified in the milk of nursing mothers. A few adverse effects on the infant have been reported, including jaundice and breast engorgement. Although no deleterious effects of the medication practice by lactation including the occurrence and number of milk should be avoided and the oral contraceptive treatment should be discontinued.

13. ADVERSE REACTIONS
Adverse reactions which have been reported include:
- Headaches
- Nausea
- Menstrual irregularities
- Spotting
- Breast tenderness
- Nystagmus
- Increased appetite
- Mental depression
- Dermatologic reactions such as acne, seborrhea, and skin rash

14. OVERDOSE
Serious effects have occurred following acute ingestion of large amounts of oral contraceptives. Such overdoses may cause nausea, vomiting, and altered bowel habits.

15. DOSE AND ADMINISTRATION

Dosage and administration may be taken on a continuous basis or on an intermittent basis. The dosage and administration should be adjusted to meet the patient's needs and the individual's response to therapy.

Instructions for Patients
- Use the drug as directed and take it at the same time each day.
- If the patient misses a pill, she should be instructed to take it as soon as she realizes it and then continue the medication at the regular time. If she does not realize it within 12 hours, she should take the missed pill and continue with the regular schedule. If the patient misses a pill, she should be instructed to take it as soon as possible and then continue with the regular schedule.
- If the patient misses a pill, she should be instructed to take it as soon as possible and then continue with the regular schedule. If the patient misses three or more consecutive pills, she should be instructed to consult a physician or pharmacist for further advice.

Side Effects of Drug
- Mild headaches
- Nausea
- Vomiting
- Breast tenderness
- Fluid retention
- Hepatic function disturbance

REFERENCES
Get your 2023 annual Physical Exam today! Many insurance plans cover annual physical exams for adults. Call (555) 123456 for an appointment now.

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depending on medical background, age, or medical history.

GET YOUR 2023 ANNUAL PHYSICAL EXAM TODAY! MANY INSURANCE PLANS COVER ANNUAL PHYSICAL EXAMS FOR ADULTS. CALL (555) 123456 FOR AN APPOINTMENT NOW.

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*depending on medical background, age, or medical history.*
WARNINGS SIGNALS

If any of these or other adverse effects occur, call your oral contraceptive doctor immediately:

1. Sharp, deep pain; bleeding of blood or sudden increase of blackness (including a possible clot or in the leg)
2. Pain in the calf during a previous episode or in the leg
3. Clotting, pain or lump in the calf may indicate a possible leg threat
4. Blisters or swelling, usually of the palms or bottom of the feet
5. Difficulty in breathing, chest pain, or swelling of the face, arm, or leg
6. Swelling of the front part of the leg
7. Swelling of the front area of the leg
8. Swelling of the face, arm, or leg
9. Difficulty in breathing, chest pain, or swelling of the face, arm, or leg
10. Swelling of the face, arm, or leg

SIDE EFFECTS OF ORAL CONTRACEPTIVES

1. Nausea
2. Nausea
3. Nausea
4. Nausea
5. Nausea

GENERAL PRECAUTIONS

1. Missed periods
2. Use of oral contraceptives before or during earlier periods
3. Use of oral contraceptives during breast-feeding
4. Use of oral contraceptives with a history of breast-feeding
5. Use of oral contraceptives during a history of breast-feeding
6. Use of oral contraceptives during a history of breast-feeding
7. Use of oral contraceptives during a history of breast-feeding
8. Use of oral contraceptives during a history of breast-feeding

REMEMBER ORAL CONTRACEPTIVES CAN STOP WORKING!
If you are a Sunday Starter:
Keep taking Pill A for 7 days. Sunday Starter:
On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

If you miss a Sunday Starter:
If you miss 1 pill, just take the next pill as usual. If you miss 2 pills, if you miss 3 pills, if you miss 4 pills, if you miss 5 pills, if you miss 6 pills, if you miss 7 pills, if you miss 8 pills, if you miss 9 pills, if you miss 10 pills, if you miss 11 pills, if you miss 12 pills.

If you miss a Day 1 Starter:
If you miss 1 pill, just take the next pill as usual. If you miss 2 pills, if you miss 3 pills, if you miss 4 pills, if you miss 5 pills, if you miss 6 pills, if you miss 7 pills, if you miss 8 pills, if you miss 9 pills, if you miss 10 pills, if you miss 11 pills, if you miss 12 pills.

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(norgestrel and ethinyl estradiol tablets, USP, 0.3 mg/0.03 mg)

Each white tablet (21) contains norgestrel 0.3 mg and ethinyl estradiol 0.03 mg.

Tablet Dispenser

Mfg. by: Searle & Co., San Juan PR 00936
for: WATSON PHARMA
A Division of Watson Laboratories, Inc., Corona, CA 91720