

Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets



Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets, 75 mg*

*Ferrous Fumarate Tablets are not USP for dissolution and assay.
FDA Approved Patient Labeling

Guide for Using Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets

WARNING TO WOMEN WHO SMOKE
 Do not use norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.

Birth control pills help to lower the chances of becoming pregnant when taken as directed. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

What are Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets?

Norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets are birth control pills. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called norethindrone acetate.

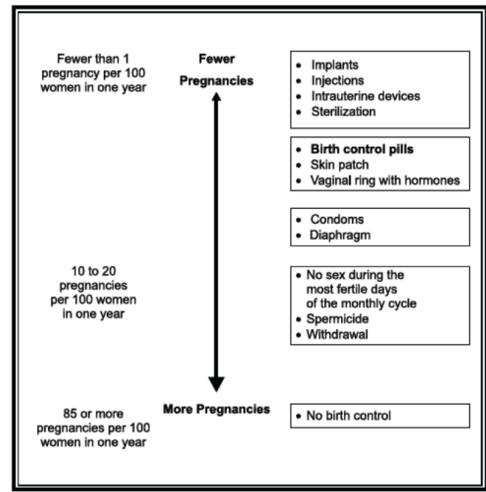
How well do Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets work?

Your chance of getting pregnant depends on how well you follow the directions for taking your birth control pills. The better you follow the directions, the less chance you have of getting pregnant.

Based on the results of one clinical study, about 2 to 4 out of 100 women may get pregnant during the first year they use norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets.

Women with a BMI above 35 kg/m² were not studied in the clinical trial, so it is not known how well norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets protect against pregnancy in such women. If you are overweight, discuss with your healthcare provider whether norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets are the best choice for you.

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.



How do I take Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets?

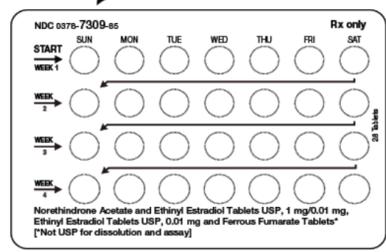
- Take one pill every day at the same time. If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.
- You may have spotting or light bleeding, or may feel sick to your stomach during the first few months of taking norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets. If you have spotting or light bleeding or 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 healthcare provider.
- Missing pills can also cause spotting or light bleeding, even when you take these missed pills later. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

- If you have trouble remembering to take norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
- If you have vomiting or diarrhea (within 3 to 4 hours after you take your pill), you should follow the instructions for "What to Do if You Miss Pills."
- If you have any questions or are unsure about the information in this leaflet, call your healthcare provider.

Before you start taking Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets

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 pill pack: The norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets pill pack has 24 "active" light violet pills (with hormones) and 2 "active" light peach pills (with hormones) for Weeks 1, 2, 3 and part of Week 4. The pill pack also has 2 "reminder" brown pills (without hormones) for the last part of Week 4.

If your period begins on a day other than Sunday, please the day label strip that starts with the first day of your period here.



TAKE PILLS IN THIS DIRECTION FROM LEFT TO RIGHT EACH WEEK

3. Find:
 - Where on the pack to start taking pills,
 - In what order to take the pills (follow the arrows), and
 - The week numbers as shown in the picture above
4. Have ready at all times:
 - Another kind of birth control (such as a condom and spermicide) to use as a back-up in case you miss pills
 - An extra pill pack

When to start the first pack of Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets

1. Take 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 the day label strip on the tablet blister over the area that has the days of the week (starting with Sunday) printed on the plastic.
3. Take the first light violet 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, because you are starting the pill at the beginning of your period. However, if you start norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets later than the first day of your period, or if you start after having a baby and you have not yet resumed your periods, you should use another method of birth control (such as a condom and spermicide) as a back-up method until you have taken 7 light violet pills

When You Switch from a Different Method of Hormonal Contraception

- When you switch from another birth control pill, start norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets on the first day you would have started your previous birth control pack.
- When you switch from a vaginal ring or skin patch, finish the 21 days of use, and wait 7 days after removal of the ring or patch before starting norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets.
- When you switch from a progestin-only pill, start norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets the next day.
- When you switch from an implant, start norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets on the day of implant removal.
- If you switch from an injectable contraceptive, start norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets on the day on which the next injection would be due.

- If you switch from an IUD, discuss with your healthcare provider when to start norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets.

What to do during the month

- 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.
- When you finish a pack of norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets, start the next pack on the day after your last brown "reminder" pill. Do not skip any days between packs.

What to do if you miss pills

Birth control pills may not be as effective if you miss any light violet or light peach pills, especially if you miss the first few or the last few light violet pills in a pack.

If you miss ONE light violet pill, follow these steps:

- Take it as soon as you remember. Take the next pill at your regular time. This means you may take two pills in 1 day.
- You do not need to use a back-up birth control method if you have sex.

If you miss TWO light violet pills in a row in Week 1 or Week 2 of your pack, follow these steps:

- Take
 1. Two pills on the day you remember and two pills the next day.
 2. One pill a day until you finish the pack.
- You could become pregnant if you have sex during the first 7 days after you restart your pills. You MUST use a non-hormonal birth control method (such as a condom and spermicide) as a back-up for those 7 days.

If you miss TWO pills (light violet or light peach) in a row in Week 3 or Week 4 of your pack, follow these steps:

- Throw out the rest of the pill pack and start a new pack 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 healthcare provider because you might be pregnant.
- You could become pregnant if you have sex during the first 7 days after you restart your pills. You MUST use a non-hormonal birth control method (such as a condom and spermicide) as a back-up for those 7 days after you restart your pills.

If you miss THREE OR MORE pills (light violet or light peach) in a row at any time, follow these steps:

- Throw out the rest of the pill pack and start a new pack 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 healthcare provider because you might be pregnant.
- You could become pregnant if you have sex on the days when you missed pills or during the first 7 days after restarting your pills. You MUST use a non-hormonal birth control method (such as a condom and spermicide) as a back-up the next time you have sex and for the first 7 days after you restart your pills.

If you forget either of the 2 brown "reminder" pills in Week 4, follow these steps:

- Throw away the pills you missed.
- Keep taking one pill each day until the pack is empty.
- You do not need to use a back-up method of birth control.

If you are still not sure what to do about the pills you have missed:

- Use a back-up method of birth control anytime you have sex.
- Keep taking one pill each day until you can reach your healthcare provider.

Who should not take Norethindrone Acetate and Ethinyl Estradiol Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets?

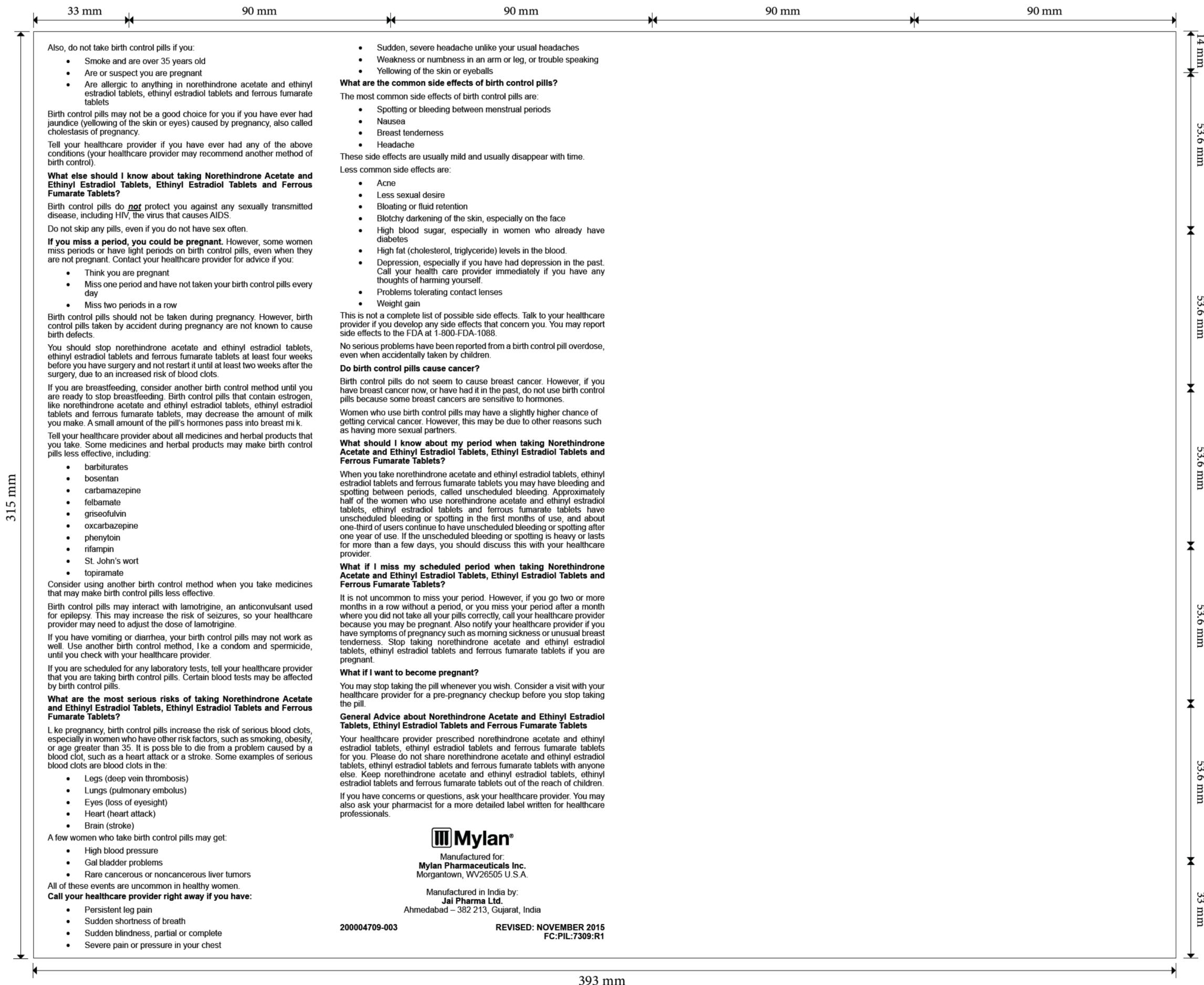
Your healthcare provider will not give you norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets if you have:

- Ever had blood clots in your legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis)
- Ever had a stroke
- Ever had a heart attack
- Certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
- An inherited problem with your blood that makes it clot more than normal
- High blood pressure that medicine can't control
- Diabetes with kidney, eye, nerve, or blood vessel damage
- Ever had certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision
- Ever had breast cancer or any cancer that is sensitive to female hormones
- Liver disease, including liver tumors

Font Specification
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 Arial 8 pt.

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 After Folding Size : 90 mm x 53 mm
 Item Code : 200004709

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