Lo Loestrin Fe is a birth control pill used for the prevention of pregnancy. If you are moderately obese, discuss with your healthcare provider whether Lo Loestrin Fe is appropriate for you.

Not ready to get pregnant? **WE’RE WITH you.**

**IMPORTANT RISK INFORMATION**

**WARNING TO WOMEN WHO SMOKE**

Do not use Lo Loestrin Fe 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.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.
Today, your way.
Finding the birth control that may be right for you.

If pregnancy isn’t part of the plan right now, we get it. In fact, it’s why we’re here. Lo Loestrin® Fe is a birth control pill created to provide effective pregnancy prevention with the lowest amount of daily estrogen\(^1\) (10 micrograms) available.

Wondering if a low-dose birth control pill may be right for you? Lo Loestrin Fe is only available with a prescription, so talk to your healthcare provider about it today.

To-date, Lo Loestrin Fe is the #1-prescribed birth control pill by OB/GYNs.\(^2\)

**Important Risk Information (continued)**

**Who should not take Lo Loestrin Fe?**
Do not use Lo Loestrin Fe if you have or have had blood clots, history of heart attack or stroke, high blood pressure that medicine cannot control, breast cancer or any cancer that is sensitive to female hormones, liver disease or liver tumors, unexplained bleeding from the vagina, if you are or may be pregnant, or if you take Hepatitis C drugs containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, as this may increase levels of liver enzymes in the blood.

**Nearly 2.5 million.**
Lo Loestrin Fe is a prescription birth control pill with no generic equivalent available that has been prescribed to nearly 2.5 million women.\(^3\)

**Survey says.**
A survey of more than 1,000 U.S. women age 18-45 including current and potential birth control pill users found that 78% of women worry\(^*\) about the amount of hormones they’re exposed to through the use of pills and 93% are interested\(^†\) in a pill with the lowest amount of daily estrogen.\(^5\)

\(^*\) Survey respondents could choose from the following to indicate their level of worry about the amount of hormones they are exposed to through the use of OCs: extremely worried, very worried, somewhat worried and not at all worried. The 78% value represents those who answered extremely worried, very worried, and somewhat worried.

\(^†\) Survey respondents could choose from the following to indicate their interest in an OC with the lowest amount of daily estrogen: extremely interested, very interested, somewhat interested, and not at all interested. The 93% value represents those who answered extremely interested, very interested, and somewhat interested.

**Important Risk Information (continued)**

**What else should I know about taking Lo Loestrin Fe?**
Treatment with Lo Loestrin Fe should be stopped if you have a blood clot, and at least 4 weeks before and through 2 weeks after major surgery. You should not take Lo Loestrin Fe any earlier than 4 weeks after having a baby, or if you are breastfeeding. If you experience yellowing of the skin or eyes due to problems with your liver, you should stop taking Lo Loestrin Fe. If you are pre-diabetic or diabetic, your doctor should monitor you while using Lo Loestrin Fe. Your doctor should evaluate you if you have any significant change in headaches or irregular menstrual bleeding.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.
Establishing a routine.
Diving into the day-to-day.

Before you consider incorporating Lo Loestrin® Fe into your daily routine, we want to help you understand the ins and outs of our ultra-low-dose birth control pill:

- Lo Loestrin Fe offers pregnancy prevention with the lowest amount of daily estrogen (10 micrograms) available.
- Lo Loestrin Fe contains a combination of 2 female hormones: an estrogen called ethinyl estradiol and a progestin called norethindrone acetate.

Helpful reminders

We never want taking your pill to feel like a chore. Here are a few tips to make your routine as seamless as possible:

- **Don’t wait ‘til it’s too late!** Always refill and pick up your prescription before you finish your current 28-day pill pack.
- **Let your phone be your friend.** Set an alert on your phone to remind you to take your pill each day and/or to remind you to pick up your next pack.
- **Don’t panic.** If you miss a pill, take the missed pill as soon as you remember. Then, take the next pill at your regular time, even if it means taking two pills in one day.
- **Keep a routine.** If you miss pills, you could get pregnant. This includes starting the pill pack late. The more pills you miss, the more likely you are to get pregnant. If you have any questions about any pills you have missed, use a back-up method of birth control anytime you have sex and keep taking one pill each day until you can reach your healthcare provider.

IMPORTANT RISK INFORMATION (continued)

What are the possible side effects of Lo Loestrin Fe?
The most common side effects reported by women taking Lo Loestrin Fe in a study were nausea/vomiting, headache, spotting or bleeding between menstrual periods, painful menstruation, weight change, breast tenderness, acne, abdominal pain, anxiety, and depression.

IMPORTANT RISK INFORMATION (continued)

What are the most serious risks of taking Lo Loestrin Fe?
Lo Loestrin Fe increases the risk of serious conditions including blood clots, stroke, and heart attack. These can be life-threatening or lead to permanent disability.

Give it time.

When you first start taking birth control pills, your body may need time to adjust. The adjustment can take a few months. If you have any concerns, contact your healthcare provider.

Once you determine whether or not you are ready to begin taking Lo Loestrin Fe, decide what time of day you plan to take your pill. Consistency is key! Take your pill at the same time every day and in the order as directed on your pill pack.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.
We hope you feel you now have the tools you need to make the birth control decision that’s right for you. We’re with you, here to make the process straightforward by offering support. While you should always refer to your healthcare provider for any questions you may have, allow us to answer some frequently asked questions about Lo Loestrin® Fe:

FAQs

Will Lo Loestrin Fe cause weight gain or depression?
We (understandably) get this question a lot! Women taking Lo Loestrin Fe have reported instances of weight gain and depression. In fact, in a clinical study around 4% of women reported changes in weight and 2% reported anxiety or depression when taking Lo Loestrin Fe.

The most common side effects reported by women taking Lo Loestrin Fe in a study were nausea/vomiting (7%), headache (7%), spotting or bleeding between menstrual periods (5%), painful menstruation (4%), weight change (4%), breast tenderness (4%), acne (3%), abdominal pain (3%), anxiety (2%), and depression (2%).

How common is breakthrough bleeding?
Approximately half of the women who use Lo Loestrin Fe have unscheduled bleeding or spotting in the first months of use, with frequency of the bleeding and spotting between periods decreasing over time. About one-third of users continue to have unscheduled bleeding or spotting after one year of use. If the unscheduled bleeding or spotting is heavy or lasts for more than a few days, you should discuss this with your healthcare provider.

Will Lo Loestrin Fe cause missed periods?
It’s not uncommon to miss a period while on birth control pills. In a clinical study, about half the women taking Lo Loestrin Fe experienced a missed period by the end of 1 year. If you miss a period, you could be pregnant. However, some women miss their periods or have light periods on birth control pills, even when they are not pregnant. Contact your healthcare provider if you think you might be pregnant, if you miss a period and have not taken your pills every day, or if you miss two periods or more in a row.

Birth control pills do not protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.
Important Risk Information

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.


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LOL107807_v2 10/17
Lo Loestrin® Fe
(norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets)

Brief Summary of FDA-Approved Patient Labeling

**WARNING TO WOMEN WHO SMOKE**

Do not use Lo Loestrin Fe 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 is Lo Loestrin Fe?**

Lo Loestrin Fe is a prescription birth control pill. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called norethindrone acetate.

**Who should not take Lo Loestrin Fe?**

Your healthcare provider will not give you Lo Loestrin Fe 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
- Take any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme “alanine aminotransferase” (ALT) in the blood

Also, do not take birth control pills if you:
- Smoke and are over 35 years old
- Are or suspect you are pregnant
- Are allergic to anything in Lo Loestrin Fe

Birth control pills may not be a good choice for you if you have ever had jaundice (yellowing of the skin or eyes) caused by pregnancy, also called cholestasis of pregnancy.

Tell your healthcare provider if you have ever had any of the above conditions (your healthcare provider may recommend another method of birth control).

**What else should I know about taking Lo Loestrin Fe?**

Birth control pills do not protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

Do not skip any pills, even if you do not have sex often.

If you miss a period, you could be pregnant. However, some women miss periods or have light periods on birth control pills, even when they are not pregnant. Contact your healthcare provider.

If you miss a period, you could be pregnant. Contact your healthcare provider immediately if you have any thoughts of harming yourself.

Contact your healthcare provider if you have any of the following:
- Persistent leg pain
- Sudden shortness of breath
- Sudden blindness, partial or complete
- Severe pain or pressure in your chest
- Sudden, severe headache unlike your usual headaches
- Weakness or numbness in arm or leg, or trouble speaking
- Yellowing of the skin or eyeballs

**What are the common side effects of birth control pills?**

The most common side effects of birth control pills are:
- Spotting or bleeding between menstrual periods
- Nausea
- Breast tenderness
- Headache

These side effects are usually mild and usually disappear with time.

**Less common side effects are:**
- Acne
- Less sexual desire
- Bloating or fluid retention
- Blotchy darkening of the skin, especially on the face
- High blood sugar, especially in women who already have diabetes
- High fat (cholesterol, triglyceride) levels in the blood
- Depression, especially if you have had depression in the past. Call your healthcare provider immediately if you have any thoughts of harming yourself
- Problems tolerating contact lenses
- Weight gain

This is not a complete list of possible side effects. Talk to your healthcare provider if you develop any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

No serious problems have been reported from a birth control pill overdose, even when accidentally taken by children.

**Do birth control pills cause cancer?**

Birth control pills do not seem to cause breast cancer. However, if you have breast cancer now, or have had it in the past, do not use birth control pills because some breast cancers are sensitive to hormones.

Women who use birth control pills may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

**What should I know about my period when taking Lo Loestrin Fe?**

When you take Lo Loestrin Fe you may have bleeding and spotting between periods, called unscheduled bleeding. Approximately half of the women who use Lo Loestrin Fe have unscheduled bleeding or spotting in the first months of use, and about one-third of users continue to have unscheduled bleeding or spotting after one year of use. If the unscheduled bleeding or spotting is heavy or lasts for more than a few days, you should discuss this with your healthcare provider.

**What if I miss my scheduled period when taking Lo Loestrin Fe?**

It is not uncommon to miss your period. However, if you go two or more months in a row without a period, or you miss your period after a month where you did not take all your pills correctly, call your healthcare provider because you may be pregnant. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. Stop taking Lo Loestrin Fe if you are pregnant.

**Need More Information?**

- This summary contains important risk information about Lo Loestrin Fe. The information provided here is not comprehensive, and is not meant to take the place of your healthcare provider’s instructions. To learn more, talk about Lo Loestrin Fe with your healthcare provider or pharmacist.
- The FDA-approved product labeling can be found at www.loloestrin.com or call 1-800-678-1605.

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LOL106948_v2 08/17

Some examples of serious blood clots are blood clots in the:
- Legs (deep vein thrombosis)
- Lungs (pulmonary embolism)
- Eyes (loss of eyesight)
- Heart (heart attack)
- Brain (stroke)

A few women who take birth control pills may get:
- High blood pressure
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

All of these events are uncommon in healthy women.

**Call your healthcare provider right away if you have:**

- Persistent leg pain
- Sudden shortness of breath
- Sudden blindness, partial or complete
- Severe pain or pressure in your chest
- Sudden, severe headache unlike your usual headaches
- Weakness or numbness in arm or leg, or trouble speaking
- Yellowing of the skin or eyeballs

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- 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 inherent 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
- Take any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme “alanine aminotransferase” (ALT) in the blood

Also, do not take birth control pills if you:
- Smoke and are over 35 years old
- Are or suspect you are pregnant
- Are allergic to anything in Lo Loestrin Fe

Birth control pills may not be a good choice for you if you have ever had jaundice (yellowing of the skin or eyes) caused by pregnancy, also called cholestasis of pregnancy.

Tell your healthcare provider if you have ever had any of the above conditions (your healthcare provider may recommend another method of birth control).

What else should I know about taking Lo Loestrin Fe?

Birth control pills do not protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

Do not skip any pills, even if you do not have sex often.

If you miss a period, you could be pregnant. However, some women miss periods or have light periods on birth control pills, even when they are not pregnant. Contact your healthcare provider for advice if you:
- Think you are pregnant
- Miss one period and have not taken your birth control pills every day
- Miss two periods in a row

Birth control pills should not be taken during pregnancy. However, birth control pills taken by accident during pregnancy are not known to cause birth defects.

You should stop Lo Loestrin Fe at least four weeks before you have surgery and not restart it until at least two weeks after the surgery, due to an increased risk of blood clots.

If you are breastfeeding, consider another birth control method when you take medicines that may make birth control pills less effective, including:
- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John’s wort
- topiramate
- aminotransferase” (ALT) in the blood

Consider using another birth control method when you take medicines that may make birth control pills less effective.

Birth control pills may interact with lamotrigine, an anticonvulsant used for epilepsy. This may increase the risk of seizures, so your healthcare provider may need to adjust the dose of lamotrigine.

If you have vomiting or diarrhea, your birth control pills may not work as well. Use another birth control method, like a condom and spermicide, until you check with your healthcare provider.

If you are scheduled for any laboratory tests, tell your healthcare provider that you are taking birth control pills. Certain blood tests may be affected by birth control pills.

What are the most serious risks of taking Lo Loestrin Fe?

Like pregnancy, birth control pills increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age greater than 35. It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke.