

Your doctor has prescribed Lo Loestrin® Fe

Lo Loestrin® Fe
(norethindrone acetate and ethinyl estradiol tablets,
ethinyl estradiol tablets and ferrous fumarate tablets)
1 mg/10 mcg and 10 mcg



Lo Loestrin Fe¹:

- Provides effective pregnancy prevention
- Provides the lowest amount of daily estrogen (10 mcg) available
- May provide short, lighter periods²
 - Most women had a period that lasted less than 2 days per cycle on average, and most had periods that were lighter than normal

#1-prescribed birth control pill by OB/GYNs³

- Prescribed to over 3 million women⁴



No
generic
equivalent
available⁵

What is Lo Loestrin® Fe?

Lo Loestrin Fe is a prescription 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.

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.

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.

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 additional Important Risk Information on the following page and accompanying Brief Summary, including Boxed Warning, for Lo Loestrin Fe.

Get the facts about Lo Loestrin® Fe



Will I gain weight or have mood changes, like anxiety or depression?

- In a clinical study, less than 5% of women reported changes in weight, anxiety, or depression when taking Lo Loestrin Fe¹
- The most common side effects reported by women taking Lo Loestrin Fe 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%)



Will I have breakthrough bleeding and spotting?

- It's not uncommon to have some bleeding and spotting between your periods. Approximately half of the women who use Lo Loestrin Fe have unscheduled bleeding or spotting in the first months of use, and the frequency of the bleeding and spotting between periods decreased over time. About one-third of users continue to have unscheduled bleeding or spotting after 1 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 I miss periods?

- Some women taking Lo Loestrin Fe may miss their period; this is not uncommon. In a clinical study, half of women experienced a missed period by the end of 1 year.¹ It's important to know that if you miss a period, you could be pregnant. Contact your healthcare provider if you think you are pregnant, miss a period and have not taken your pills every day, or if you miss 2 or more periods in a row

For more information about Lo Loestrin Fe and how eligible patients may be able to save on a Lo Loestrin Fe prescription, visit loloestrin.com

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.

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.

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

Please see additional Important Risk Information on the previous page and accompanying Brief Summary, including Boxed Warning, for Lo Loestrin Fe.

References: 1. Lo Loestrin® Fe prescribing information, Irvine, CA: Allergan USA, Inc.; 2017. 2. Data on file. Clinical Study Reports. Allergan USA, Inc.; Madison, NJ. 3. IQVIA: National Prescription Audit® - TRx/EURx Data: April 2018 - April 2019 (claim derived from the use of information under license from IQVIA, which expressly reserves all rights, including rights of copying, distribution, and republication). 4. IQVIA: National Prescription Audit® - Patient Insights NTB Data: December 2010 - April 2019 (claim derived from the use of information under license from IQVIA, which expressly reserves all rights, including rights of copying, distribution, and republication). 5. US Food and Drug Administration. The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available from: <https://www.accessdata.fda.gov/scripts/cder/ob/>. Accessed July 25, 2019.



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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 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 until you are ready to stop breastfeeding. Birth control pills that contain estrogen, like Lo Loestrin Fe, may decrease the amount of milk you make. A small amount of the pill's hormones pass into breast milk.

Tell your healthcare provider about all medicines and herbal products that you take. Some medicines and herbal products may make birth control pills less effective, including:

- barbiturates
- griseofulvin
- St. John's wort
- bosentan
- oxcarbazepine
- topiramate
- carbamazepine
- phenytoin
- felbamate
- rifampin

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.

Some examples of serious blood clots are blood clots in the:

- Legs (deep vein thrombosis)
- Lungs (pulmonary embolus)
- 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 an 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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