

## FDA-Approved Patient Labeling

### Guide for Using Lo Loestrin<sup>®</sup> Fe

#### 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 birth control pill. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called norethindrone acetate.

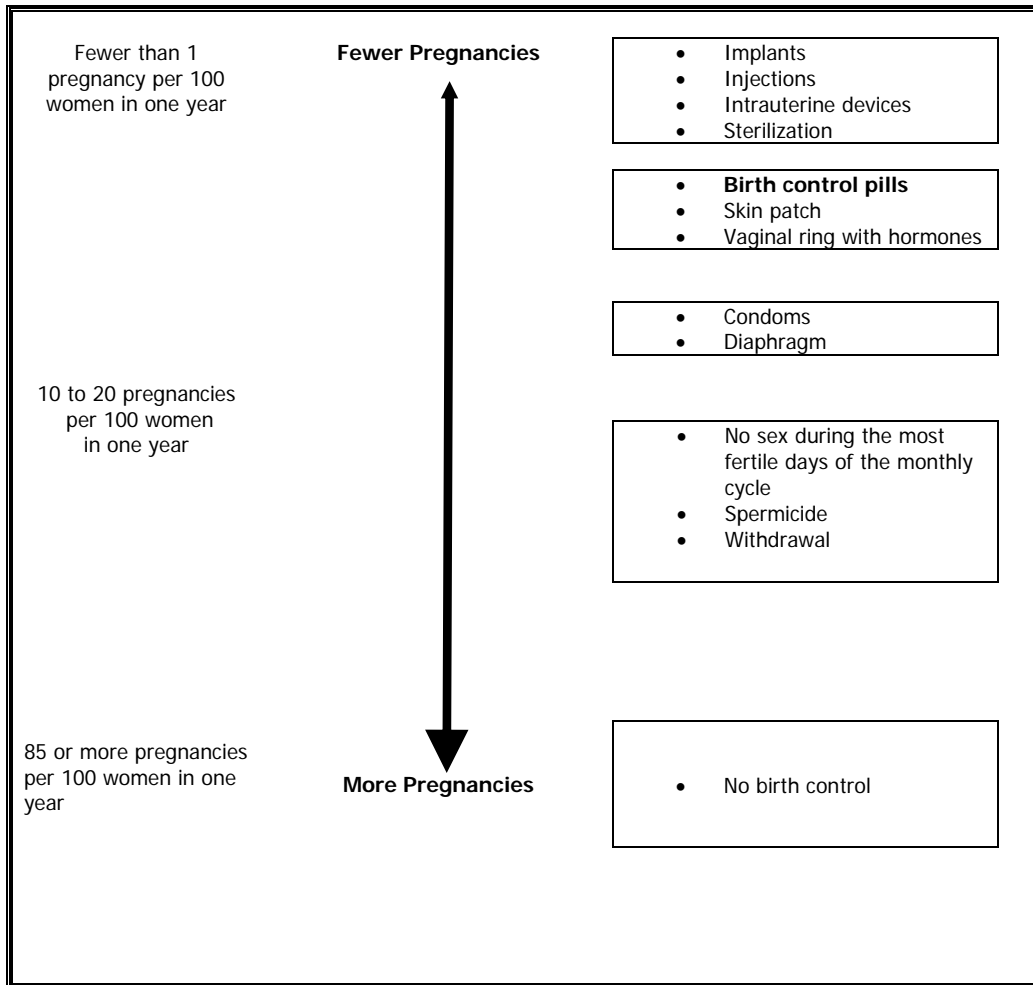
#### **How well does Lo Loestrin Fe work?**

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 Lo Loestrin Fe.

Women with a BMI above 35 kg/m<sup>2</sup> were not studied in the clinical trial, so it is not known how well Lo Loestrin Fe protects against pregnancy in such women. If you are overweight, discuss with your healthcare provider whether Lo Loestrin Fe is 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 Lo Loestrin Fe?

- 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 Lo Loestrin Fe. 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 Lo Loestrin Fe, 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”.

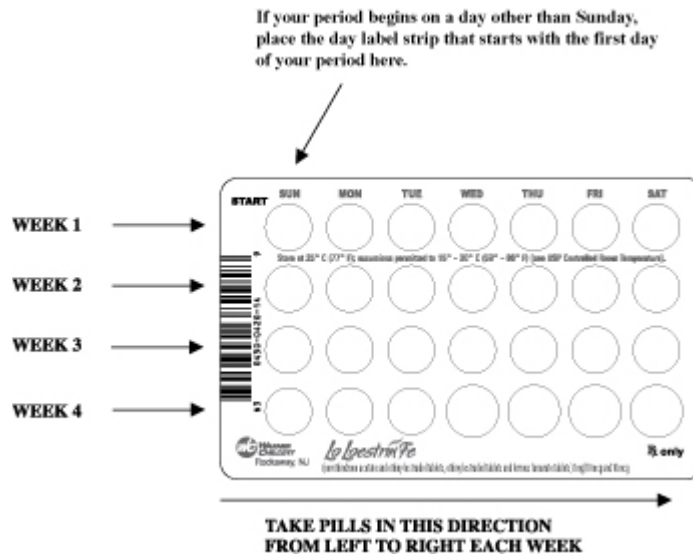
- If you have any questions or are unsure about the information in this leaflet, call your healthcare provider.

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### **Before you start taking Lo Loestrin Fe**

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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 Lo Loestrin Fe pill pack has 24 "active" blue pills (with hormones) and 2 "active" white 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.



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

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### **When to start the *first* pack of Lo Loestrin Fe**

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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 dispenser over the area that has the days of the week (starting with Sunday) printed on the plastic.
3. Take the first blue 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 Lo Loestrin Fe 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 blue pills.

### **When You Switch from a Different Method of Hormonal Contraception**

- When you switch from another birth control pill, start Lo Loestrin Fe 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 Lo Loestrin Fe.
- When you switch from a progestin-only pill, start Lo Loestrin Fe the next day.
- When you switch from an implant, start Lo Loestrin Fe on the day of implant removal.
- If you switch from an injectable contraceptive, start Lo Loestrin Fe 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 Lo Loestrin Fe.

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### **What to do during the month**

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- 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 Lo Loestrin Fe, start the next pack on the day after your last brown "reminder" pill. Do not skip any days between packs.

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### **What to do if you miss pills**

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

#### **If you miss ONE blue 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 blue 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 (blue or white) 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 (blue or white) 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 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

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
- bosentan

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

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.

### **What if I want to become pregnant?**

You may stop taking the pill whenever you wish. Consider a visit with your healthcare provider for a pre-pregnancy checkup before you stop taking the pill.

### **General Advice about Lo Loestrin Fe**

Your healthcare provider prescribed Lo Loestrin Fe for you. Please do not share Lo Loestrin Fe with anyone else. Keep Lo Loestrin Fe out of the reach of children. If you have concerns or questions, ask your healthcare provider. You may also ask your pharmacist for a more detailed label written for healthcare professionals.

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**To report SUSPECTED ADVERSE REACTIONS, contact Warner Chilcott at 1-800-521-8813 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

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