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.

*If you are moderately obese, discuss with your healthcare provider whether Lo Loestrin Fe is appropriate for you.

IMPORTANT RISK INFORMATION

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

Three words: short, lighter periods.

- While taking Lo Loestrin Fe, most women had a period that lasted LESS THAN 2 DAYS per cycle on average.²
- Some women also experienced periods that were LIGHTER THAN NORMAL.⁴

How common is breakthrough bleeding?

About half of the women who use Lo Loestrin Fe have unscheduled bleeding or spotting in the first months of use. The frequency of their bleeding and spotting between periods decreased over time. In about one-third of women, unscheduled bleeding or spotting continued after one year of use. If the unscheduled bleeding or spotting is heavy or lasts for more than a few days, you should discuss it with your healthcare provider.²

Will Lo Loestrin Fe cause missed periods?

It’s not uncommon to miss a period while on birth control pills. In a clinical study, 49% of the women taking Lo Loestrin Fe experienced a missed period by the end of the first year.² 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 2 periods or more in a row.

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.
Lo Lo. Once a day. Every day.

Once you and your healthcare provider decide whether Lo Loestrin Fe is right for you, choose what time of day to begin taking your pill. Then take it at the same time every day in the order as directed on your pill pack. Get into a routine and stick to it. You shouldn’t miss a day.

How not to forget.
It’s really important to take Lo Loestrin Fe every day. Here are a few tips to follow:

- Always refill early and pick up your prescription before you finish your 28-day pill pack.
- Set an alert on your phone to remind you to take your pill each day and remind you to pick up your next pack.
- If you miss one blue 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. If you have further questions, please see the enclosed Brief Summary or consult your healthcare provider.
- Stick to the 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 any time 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.

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

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.
Pill Pack 101.

Lo Loestrin® Fe is an “extended regimen” pill. It has 26 days of “active pills” and 2 days of “reminder pills.” Here’s how the pill pack looks.

Each pill pack has 24 “active” blue pills (with hormones) plus 2 “active” white pills (with hormones) that you’ll take weeks 1 through 3, and part of week 4. Then you’ll take the 2 “reminder” brown pills (without hormones) for the last part of week 4.

Like other birth control pills, you should take a Lo Loestrin Fe pill every day, for 28 days, until the pack is empty. Then you start a new pill pack. Remember to refill your prescription before you run out.

Take pills in this direction — from left to right each week.²

What about weight gain and depression?

We get this question a lot! In a clinical study, around 4% of women reported changes in weight. 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%).

Low-dose. Women want to know.

In a survey of more than 1000 current and potential birth control pill users³:

- 78% of women worry⁷ about the amount of hormones they’re exposed to through the use of pills.
- 93% are interested⁶ in a pill with the lowest amount of daily estrogen.

²Online survey conducted by The Harris Poll on behalf of Allergan USA, Inc., between July 7-14, 2014, among 1005 U.S. women age 18-45 currently using oral contraceptives (OCs) or considering use in the next 6 months.

³Survey 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 oral contraceptives: 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.

⁴Survey 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)

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.

Lo Loestrin® Fe

(norethindrone acetate and ethinyl estradiol tablets; ethinyl estradiol tablets and ferrous fumarate tablets) 1 mg/10 mcg and 10 mcg
Please see Program Terms, Conditions, and Eligibility Criteria at LoLoSavings.com. Maximum savings limits apply: patient out-of-pocket expense will vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs.

What is Lo Loestrin Fe?
Lo Loestrin Fe is indicated for pregnancy prevention. 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.

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

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 immediately if you have any thoughts of harming yourself.

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 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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