

FDA-APPROVED PATIENT LABELING

Guide for Using Kaitlib™ Fe [KATE-lib EFF EE] (norethindrone and ethinyl estradiol chewable tablets and ferrous fumarate chewable tablets)

WARNING TO WOMEN WHO SMOKE

Do not use Kaitlib 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 Kaitlib Fe?

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

How Do I Take Kaitlib Fe?

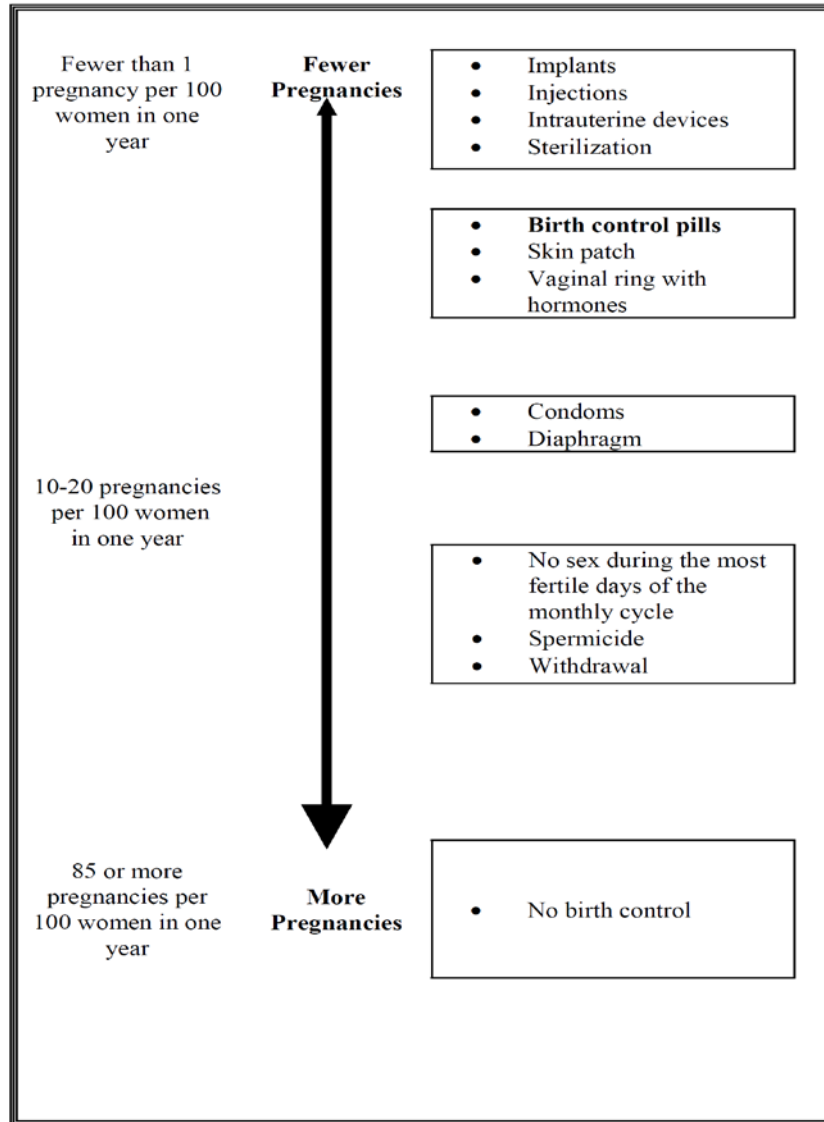
- Chew and swallow one pill every day without water at the same time. Take the pills in the order directed on the blister.
- Do not skip pills or take at intervals exceeding 24 hours. If you miss pills (including starting the pack late), you could get pregnant. The more pills you miss, the more likely you are to get pregnant.
- If you have trouble remembering to take Kaitlib Fe, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
- You may have spotting or light bleeding when you first take Kaitlib Fe. Spotting or light bleeding is normal at first.
- You may feel sick to your stomach (nauseated), especially during the first few months that you take Kaitlib Fe. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If your nausea doesn't go away, call your healthcare provider.
- If you vomit or have diarrhea within 3 to 4 hours of taking your pill, follow the instructions for "What Should I Do if I Miss any Pills."
- Missing pills can also cause spotting or light bleeding, even when you take the missed pills late. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

How Well Does Kaitlib Fe Work?

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

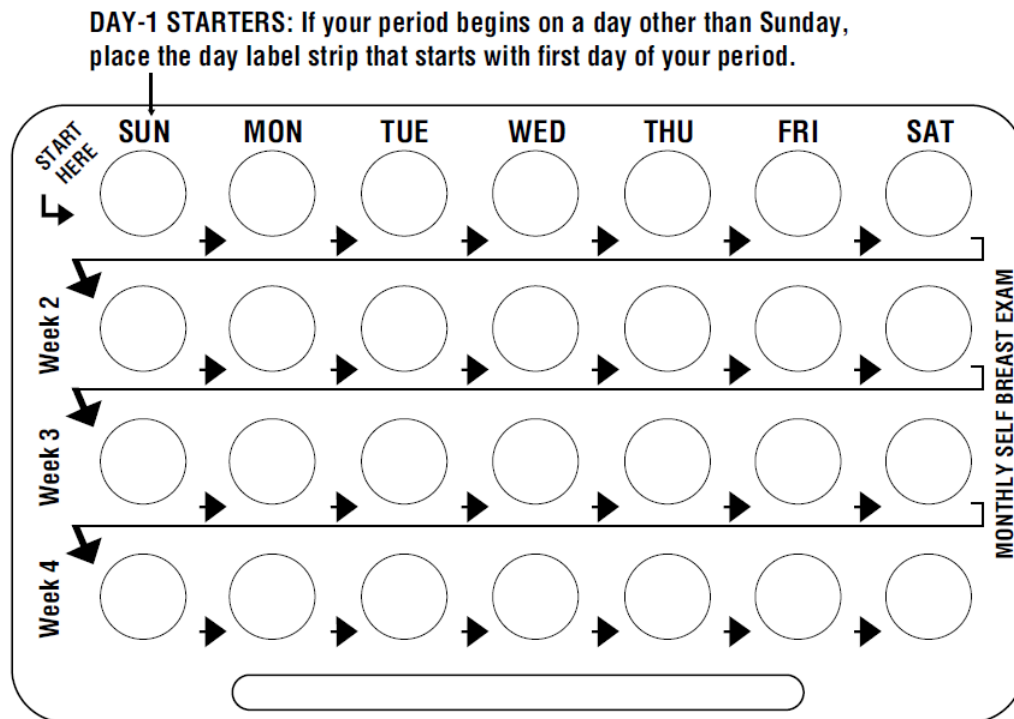
Based on the results of one clinical study, 1 to 3 women out of 100 women may get pregnant during the first year they use Kaitlib Fe.

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.



Before you start taking Kaitlib Fe

- Decide what time of day to take your pill. It is important to take it at the same time every day and in the order as directed on the blister.



- Look at your Kaitlib Fe blister. The blister has four rows of 7 pills each, for a total of 28 pills. Find:
 - where on the pack to start taking your pills
 - in what order to take the pills

Each Kaitlib Fe blister has 28 pills

- 24 light green pills with hormones for Weeks 1, 2 and 3 and the first part of Week 4
 - 4 brown pills without hormones for the remainder of Week 4
- Be sure to 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.

When to Start Kaitlib Fe

If you start taking Kaitlib Fe and you did not use a hormonal birth control method before:

DAY-1 START:

- Pick 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). Pick a time of day that will be easy to remember.
- Place this day label strip on the blister over the area that has the days of the week (starting with Sunday) printed on the blister.
- Take the first light green pill of the first pack during the first 24 hours of your period.
- 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 on a day other than the first day

of your period or if you are starting after having been pregnant and have not yet had a period, use a back-up method of birth control such as a condom and spermicide until you have taken a light green pill for 7 days in a row.

- After taking the last brown pill (day 28) of the blister, start taking the first light green pill from a new blister the very next day whether or not you are having your period.

If you start taking Kaitlib Fe and you are switching from a combination hormonal method such as:

- another pill
- vaginal ring
- patch
- Take the first light green pill on the first day you would have started your previous birth control pack.
- If you previously used a vaginal ring or transdermal patch, finish the 21 days of use and wait 7 days after removal of the ring or transdermal patch before starting Kaitlib Fe.
- Use a non-hormonal back-up method such as a condom and spermicide for the first 7 days you take Kaitlib Fe.

If you start taking Kaitlib Fe and you are switching from a progestin-only method such as a:

- progestin-only pill
- implant
- intrauterine system
- injection
- Take the first light green pill on the day you would have taken your next progestin-only pill or on the day of removal of your implant or intrauterine system or on the day when you would have had your next injection.
- Use a non-hormonal back-up method such as a condom and spermicide for the first 7 days you take Kaitlib Fe.

What Should I do if I Miss any Pills

If you forgot to start a new blister, **you may already be pregnant**. Use back-up contraception (such as a condom and spermicide) anytime you have sex. Call your healthcare provider if you are unsure whether you are pregnant.

Your birth control pills may not be as effective if you miss any light green pills, and particularly if you miss the first few or the last few light green pills in a pack.

If you MISS ONE light green pill

- 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 green pills in a row in WEEK 1 or WEEK 2 of your pack

- Take two pills on the day you remember and two pills the next day.
- Then take one pill a day until you finish the pack.
- You could become pregnant if you have sex during the *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 light green pills in a row in WEEK 3 or WEEK 4 of your pack

- THROW OUT the rest of the pill pack and start a new pack that same day.
- You could become pregnant if you have sex during the *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 light green pills in a row at any time

- THROW OUT the rest of the pill pack and start a new pack that same day.
- 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 any of the four brown “reminder” pills in WEEK 4

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

You may already be pregnant or COULD BECOME PREGNANT if you had sex on the days after the pills were missed. The more pills missed and the closer they are to the end of the cycle, the higher the risk of a pregnancy. You should call your doctor or healthcare provider if you are unsure whether you are already pregnant.

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

- Call your healthcare provider
- Use a back-up contraception (such as a condom and spermicide) anytime you have sex and keep taking 1 pill each day

Who Should not Take Kaitlib Fe?

Your healthcare provider will not give you Kaitlib Fe if you have:

- Ever had breast cancer, which may be 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.
- Ever had blood clots in your arms, legs, or lungs

- 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, or blood vessel damage
- Certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Are pregnant

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).

What Else Should I Know about Taking Kaitlib 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 according to directions
- 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 Kaitlib Fe at least four weeks before you have major 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 Kaitlib 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.

What are the Most Serious Risks of Taking Birth Control Pills?

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 (thrombophlebitis)
- 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 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 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 changes

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

You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or you can visit the Lupin website at www.lupinpharmaceuticals.com.

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

Do Birth Control Pills Cause Cancer?

It is not known if hormonal birth control pills cause breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control 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 Kaitlib Fe?

Unscheduled (irregular) vaginal bleeding or spotting may occur while you are taking Kaitlib Fe. Unscheduled bleeding may vary from slight staining to breakthrough bleeding, which is a flow much like a regular period, but which occurs between menstrual periods. Unscheduled bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does

not indicate any serious problems.

Approximately one-third of the women who use Kaitlib Fe have unscheduled bleeding or spotting in the first months of use. About one-quarter of users continue to have unscheduled bleeding or spotting after one year of use.

It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle, is unusually heavy, or lasts for more than a few days, call your healthcare provider.

What if I Miss My Scheduled Period when Taking Kaitlib Fe?

Women who use Kaitlib Fe may not have a period at the end of every 28-day pack of pills.

If you miss more than two periods in a row or miss one period when you have not taken your birth control pills according to directions, call your healthcare provider. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. It is important that your healthcare provider checks you to find out if you are pregnant. Stop taking Kaitlib 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 Kaitlib Fe

Your healthcare provider prescribed Kaitlib Fe for you. Please do not share Kaitlib Fe with anyone else. Keep Kaitlib Fe out of the reach of children.

If you have concerns or questions, ask your healthcare provider. You may also ask your healthcare provider for a more detailed label written for medical professionals.

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