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2. Lybrel

Lybrel 🕬

Generic name: ethinyl estradiol and levonorgestrel [ETH-in-ill-ess-tra-DYE-ol-and-LEE-vo-nor-JESS-trel]

Brand names: Alesse, Altavera, Amethyst, Aviane, Enpresse, ... show all 18 brands

Drug class: Contraceptives

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Uses Warnings Before taking Dosage Side effects Interactions



The Lybrel brand name has been **discontinued** in the U.S. If generic versions of this product have been approved by the FDA, there may be generic equivalents available.

What is Lybrel?

Lybrel contains a combination of female hormones that prevent ovulation (the release of female hormones that prevent ovulation (the release of an egg from an ovary). Lybrel also causes changes in your cervical mucus and uterine lining, making it harder for sperm to reach the uterus and harder for a fertilized egg to attach to the uterus.

Lybrel is used as contraception to prevent pregnancy.

Lybrel may also be used for purposes not listed in this medication guide.

Warnings

Do not use Lybrel if you are pregnant or if you have recently had a baby. You should not take Lybrel if you have any of the following conditions: uncontrolled high blood pressure, heart disease, a blood-clotting disorder, circulation problems, diabetic problems with your eyes or kidneys, unusual vaginal bleeding, liver disease or liver cancer, severe migraine headaches, if you smoke and are over 35, or if you have ever had breast or uterine cancer, jaundice caused by birth control pills, a heart attack, a stroke, or a blood clot.

You may need to use back up birth control, such as condoms or a spermicide, when you first start using Lybrel or if you miss a dose. Follow your doctor's instructions.

Missing a pill increases your risk of becoming pregnant. Carefully follow the "missed dose" instructions if you forget to take a Lybrel pill.

Some drugs can make Lybrel less effective in preventing pregnancy, including antibiotics, hepatitis C medications, HIV/AIDS medications, seizure medications, or barbiturate sedatives. Tell your doctor about all other medications you use.

Before taking this medicine

Lybrel can cause birth defects. Do not use if you are pregnant. Tell your doctor right away if you become pregnant, or if you miss two menstrual periods in a row. If you have recently had a baby, wait at least 4 weeks before taking Lybrel. You should not take Lybrel if you have:

- untreated or uncontrolled high blood pressure;
- heart disease (coronary artery disease, uncontrolled heart valve disorder, history of heart attack, stroke, or blood clot);
- a blood-clotting disorder or circulation problems;
- problems with your eyes, kidneys or circulation caused by diabetes;
- a history of hormone-related cancer such as breast or uterine cancer;
- unusual vaginal bleeding that has not been checked by a doctor;
- liver disease or liver cancer;
- severe migraine headaches (with aura, numbness, weakness, or vision changes), especially if you are older than 35;
- · a history of jaundice caused by pregnancy or birth control pills; or
- if you smoke and are over 35 years old.

To make sure you can safely take Lybrel, tell your doctor if you have any of these other conditions:

- high blood pressure, varicose veins;
- · high cholesterol or triglycerides, or if you are overweight;
- a history of depression;
- · underactive thyroid;
- gallbladder disease;
- · diabetes;
- · seizures or epilepsy;
- a history of irregular menstrual cycles;
- · tuberculosis; or
- a history of fibrocystic breast disease, lumps, nodules, or an abnormal mammogram.

The hormones in Lybrel (ethinyl estradiol and levonorgestrel) can pass into breast milk and may harm a nursing baby. Lybrel may also slow breast milk production. Do not Lybrel use if you are breast feeding a baby.

1 Lybrel pregnancy and breastfeeding warnings (more detail)

How should I take Lybrel?

Take Lybrel exactly as prescribed by your doctor. Do not take in larger or smaller amounts or for longer than recommended. Follow the directions on your prescription label. Your pill pack contains 28 pills with active medication.

You will take your first Lybrel pill on the first day of your period. If your doctor directs you to start this medication on any

other day, use an additional form of non-hormonal birth control (such as condoms, spermicide) for the first 7 days to prevent pregnancy until this medication has enough time to work. If you start on the first day of your period, you do not need to use back-up birth control the first week. Follow your doctor's instructions.

Take one pill every day, no more than 24 hours apart. When the pills run out, start a new pack the following day. There is no break between packs, and there are no reminder tablets. You may get pregnant if you do not take one pill daily. Get your prescription refilled before you run out of pills completely.

You may have breakthrough bleeding, especially during the first 3 months. Tell your doctor if this bleeding continues or is very heavy.

Use a back-up birth control if you are sick with severe vomiting or diarrhea.

If you need surgery or medical tests or if you will be on bed rest, you may need to stop using Lybrel for a short time. Any doctor or surgeon who treats you should know that you are using Lybrel.

While taking Lybrel, you will need to visit your doctor regularly.

Store Lybrel at room temperature away from moisture and heat.

Detailed Lybrel dosage information

What happens if I miss a dose?

Follow the patient instructions provided in your Lybrel packet. Ask your doctor or pharmacist if you do not understand these instructions. Missing a pill increases your risk of becoming pregnant.

If you miss one Lybrel pill:

- Take the missed pill as soon as you remember, THEN take the next pill at your regular time. This means you may take 2 pills in 1 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 condoms and/or spermicide) as a back-up for those 7 days.

If you miss two Lybrel pills and remembered on the day of the second missed pill:

- Take 2 missed pills on the day you remember. The following day you are back on schedule to take 1 pill a day. For example, you take your pills in the morning and you missed 1 pill on Monday and 1 on Tuesday. On Tuesday evening you remembered that you missed your Monday and Tuesday pills. You take the 2 missed pills on Tuesday evening and on Wednesday morning you're back on schedule and you take 1 pill.
- 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 condoms and/or spermicide) as a back-up for those 7 days.

If you miss two Lybrel pills and remembered on the day after the second pill is missed:

• Take 2 missed pills on the day you remember. The next day you take 2 pills. The following day you are back on schedule to take your pills. For example, you take your pills in the morning and you missed 1 pill on Monday and 1 on Tuesday. On Wednesday morning you remembered that you missed your Monday and Tuesday pills. You take the 2 missed pills on Wednesday morning and 2 pills on Thursday morning. On Friday morning you're back on schedule and you take 1 pill.

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 condoms and/or spermicide) as a back-up for those 7 days.

If you miss three or more Lybrel pills:

- Contact your health care professional for further advice.
- · Keep taking one pill every day until you reach your health care professional. Do not take the missed pills.
- 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 condoms and/or spermicide) as a back-up for those 7 days

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. Overdose symptoms may include nausea, vomiting, and vaginal bleeding.

What should I avoid?

Smoking can increase your risk of blood clots, stroke, or heart attack caused by Lybrel, especially if you are older than 35.

Lybrel will not protect you from sexually transmitted diseases--including HIV and AIDS. Using a condom is the only way to protect yourself from these diseases.

Lybrel side effects

Get emergency medical help if you have any of these signs of an allergic reaction to Lybrel: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Stop using Lybrel and call your doctor at once if you have a serious side effect such as:

- sudden numbness or weakness, especially on one side of the body;
- sudden and severe headache, confusion, problems with vision, speech, or balance;
- chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea, sweating, general ill feeling;
- sudden cough, wheezing, rapid breathing, coughing up blood;
- pain, swelling, warmth, or redness in one or both legs;
- a change in the pattern or severity of migraine headaches;
- nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- · swelling in your hands, ankles, or feet;
- · a breast lump; or
- symptoms of depression (sleep problems, weakness, tired feeling, mood changes).

Less serious Lybrel side effects may include:

- mild nausea (especially when you first start taking this medicine), vomiting, bloating, stomach cramps;
- breast tenderness or swelling, nipple discharge;
- freckles or darkening of facial skin, increased hair growth, loss of scalp hair;
- · changes in weight or appetite;
- · problems with contact lenses;
- · vaginal itching or discharge; or
- changes in your menstrual periods, decreased sex drive.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

1 Lybrel side effects (more detail)

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What other drugs will affect Lybrel?

Some drugs can make Lybrel less effective, which may result in pregnancy. Before using Lybrel, tell your doctor if you are using any of the following drugs:

- bosentan (Tracleer);
- an antibiotic or tuberculosis medication;

- drugs to treat hepatitis C, HIV, or AIDS;
- phenobarbital (Solfoton) and other barbiturates;
- St. John's wort; or
- · seizure medications.

Tell your doctor about all other medicines you use, especially:

- dantrolene (Dantrium);
- tizanidine (Zanaflex); or
- tranexamic acid (Cyklokapron, Lysteda).

This list is not complete and other drugs may interact with Lybrel. Tell your doctor about all medications you use. This includes prescription, over-the-counter, vitamin, and herbal products. Do not start a new medication without telling your doctor.

Lybrel drug interactions (more detail)

Does Lybrel interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Lybrel
+
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More about Lybrel (ethinyl estradiol / levonorgestrel)

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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Lybrel only for the indication prescribed.

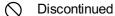
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DRUG STATUS

Availability



Pregnancy & Lactation

ം Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

□ Drug history at FDA

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