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Safyral

Safyral

Generic name: drospirenone, ethinyl estradiol, and levomefolate [droe-SPYE-re-none, ETH-in-il-ES-tra-DYE-ol, and-LEE-voe-me-FOE-

late-1

Brand names: Beyaz, Safyral Drug class: Contraceptives

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What is Safyral?

Safyral contains a combination of drospirenone, ethinyl estradiol, and levomefolate. Drospirenone and ethinyl estradiol prevent ovulation (the release of an egg from an ovary) and also cause 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. Levomefolate is a type of B vitamin that helps prevent a rare birth defect that could occur in a baby if pregnancy occurs while taking birth control pills or shortly after stopping them.

Safyral is used as contraception to prevent pregnancy.

Safyral is used in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels to lower their risk of having a pregnancy with a rare type of birth defect (known as a neural tube defect).

Warnings

Do not use Safyral if you are pregnant or if you recently had a baby.

You should not take Safyral if you have: an adrenal gland disorder, kidney disease, uncontrolled high blood pressure, heart disease, coronary artery disease, circulation problems (especially with diabetes), undiagnosed vaginal bleeding, liver disease or liver cancer, severe migraine headaches, if you also take certain hepatitis C medication, if you will have major surgery, if you smoke and are over 35, or if you have ever had a heart attack, a stroke, a blood clot, jaundice caused by pregnancy or birth control pills, or cancer of the breast, uterus/cervix, or vagina.

Taking Safyral can increase your risk of blood clots, stroke, or heart attack.

Smoking can greatly increase your risk of blood clots, stroke, or heart attack. You should not take Safyral if you smoke and are over 35 years old.

Safyral side effects

Get emergency medical help if you have signs of an allergic reaction to Safyral: hives; difficult breathing; swelling of

your face, lips, tongue, or throat.

Stop using Safyral and call your doctor at once if you have:

- signs of a stroke sudden numbness or weakness (especially on one side of the body), sudden severe headache, slurred speech, problems with vision or balance;
- signs of a blood clot sudden vision loss, stabbing chest pain, feeling short of breath, coughing up blood, pain or warmth in one or both legs;
- heart attack symptoms chest pain or pressure, pain spreading to your jaw or shoulder, nausea, sweating;
- liver problems loss of appetite, upper stomach pain, tiredness, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- increased blood pressure severe headache, blurred vision, pounding in your neck or ears;
- swelling in your hands, ankles, or feet;
- a change in the pattern or severity of migraine headaches; or
- symptoms of depression sleep problems, weakness, tired feeling, mood changes.

Common Safyral side effects may include:

- nausea;
- · breast tenderness;
- · headache; or
- breakthrough bleeding.

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.

Safyral side effects (more detail)

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Before taking this medicine

Taking Safyral can increase your risk of blood clots, stroke, or heart attack. You are even more at risk if you have high blood pressure, diabetes, high cholesterol, or if you are overweight. Your risk of stroke or blood clot is highest during your first year of taking Safyral. Your risk is also high when you restart this medicine after not taking it for 4 weeks or longer.

Smoking can greatly increase your risk of blood clots, stroke, or heart attack. Your risk increases the older you are and the more you smoke. You should not take Safyral if you smoke and are over 35 years old.

Do not use if you are pregnant. Stop using Safyral and tell your doctor right away if you become pregnant, or if you miss 2 menstrual periods in a row. If you have recently had a baby, wait at least 4 weeks before taking Safyral.

You should not take Safyral if you have:

- · an adrenal gland disorder;
- · kidney disease;
- untreated or uncontrolled high blood pressure;
- heart disease (coronary artery disease, history of heart attack, stroke, or blood clot);
- an increased risk of having blood clots due to a heart problem or a hereditary blood disorder;
- circulation problems (especially if caused by diabetes);
- a history of hormone-related cancer, or cancer of the breast, uterus/cervix, or vagina;
- 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;
- if you smoke and are over 35 years old; or
- if you take any hepatitis C medication containing ombitasvir/paritaprevir/ritonavir (Technivie).

To make sure Safyral is safe for you, tell your doctor if you have ever had:

- heart problems, high blood pressure, or if you are prone to having blood clots;
- high levels of potassium in your blood;
- high cholesterol or triglycerides, or if you are overweight;
- depression;
- liver or kidney disease;

- underactive thyroid, diabetes, gallbladder disease; or
- a migraine headache.

The hormones in Safyral can pass into breast milk and may harm a nursing baby. Safyral may also slow breast milk production. Do not use if you are breast feeding.

Safyral pregnancy and breastfeeding warnings (more detail)

How should I take Safyral?

Take Safyral exactly as prescribed by your doctor. Follow all directions on your prescription label. Do not take this medicine in larger or smaller amounts or for longer than recommended. Take your first pill on the first day of your period or on the first Sunday after your period begins. You may need to use back-up birth control, such as condoms with spermicide, when you first start using this medication.

Take one pill every day, no more than 24 hours apart. When the pills run out, start a new pack the following day. You could get pregnant if you do not take one pill daily.

You must take the pills in the right order for Safyral to be effective in preventing pregnancy. Follow the arrows shown on each row of pills in your blister pack. The last few pills you will take contain only levomefolate and not the contraceptive (birth control) medicines.

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

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

If you need major surgery or will be on long-term bed rest, you may need to stop using this medicine for a short time. Any doctor or surgeon who treats you should know that you are using Safyral.

Store at room temperature away from moisture and heat.

Dosing information

Usual Adult Dose for Contraception:

1 tablet orally each day. A patient should begin taking either on the first day of the menstrual period (Day 1 Start) or on the first Sunday after the onset of the menstrual period (Sunday Start). The patient should begin the next and all subsequent 28-day regimens on the same day of the week as she began the first regimen, following the same schedule.

Detailed Safyral dosage information

What happens if I miss a dose?

Follow the patient instructions provided with your medicine. Ask your doctor or pharmacist if you do not understand these instructions. Missing a pill increases your risk of becoming pregnant. If you miss 1 pill during Week 1, 2, or 3, take 2 pills on the day that you remember. Then take 1 pill per day for the rest of the pack.

If you miss 2 pills in a row in Week 1 or 2, take 2 pills per day for 2 days in a row. Then take 1 pill per day for the rest of

the pack. Use back-up birth control for at least 7 days following the missed pills.

If you miss 2 pills in a row in Week 3, throw out the rest of the pack and start a new pack the same day if you are a Day 1 starter. If you are a Sunday starter, keep taking a pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack that day.

If you miss 3 pills in a row in Week 1, 2, or 3, throw out the rest of the pack and start a new pack on the same day if you are a Day 1 starter. If you are a Sunday starter, keep taking a pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack that day.

If you miss two or more pills, you may not have a period during the month. If you miss a period for two months in a row, call your doctor because you might be pregnant.

If you miss a levomefolate pill in Week 4, throw the pill away and keep taking 1 pill per day until the pack is empty.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. Overdose may cause nausea or vaginal bleeding.

What to avoid

Do not smoke while taking Safyral, especially if you are older than 35 years of age.

Safyral 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.

What other drugs will affect Safyral?

Other drugs may interact with drospirenone, ethinyl estradiol, and levomefolate, including prescription and over-the-counter medicines, vitamins, and herbal products. Some drugs can make this medicine less effective, which may result in pregnancy. Tell your doctor about all your current medicines and any medicine you start or stop using.

Safyral drug interactions (more detail)

Does Safyral interact with my other drugs?

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

Safyral	
+	
Enter a drug name	Add

More about Safyral (drospirenone / ethinyl estradiol / levomefolate calcium)

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Other brands

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Other brands

Beyaz, Tydemy, Rajani

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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 Safyral only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

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Availability

Rx Prescription only

Pregnancy & Lactation

ন্য Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

The Drug history at FDA

User Reviews & Ratings

5.9 / 10

67 Reviews

Images

Safyral levomefolate calcium 0.451 mg (M+)





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