

Package leaflet: Information for the patient

Lynkuet 60 mg soft capsules elinzanetant

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lynkuet is and what it is used for
2. What you need to know before you take Lynkuet
3. How to take Lynkuet
4. Possible side effects
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1. What Lynkuet is and what it is used for

Lynkuet contains the active substance elinzanetant, which is not a hormone. It is used to treat women going through menopause changes who experience moderate to severe vasomotor symptoms.

Vasomotor symptoms are sudden feelings of warmth or intense heat, mainly in the face, neck and chest and sweating during day or night, also called hot flushes or night sweats.

How Lynkuet works

Oestrogens are hormones made by a woman's ovaries. The ovaries normally stop making oestrogens when a woman is in menopause. Before menopause, a balance exists between oestrogen and certain substances acting on so-called Kisspeptin/Neurokinin B/Dynorphin neurons in the brain. These neurons help regulate body temperature and sleep. During menopause, when oestrogen levels decline, this balance is disrupted making these neurons more active than usual. This can cause hot flushes and sleep problems. By lowering the activity of these neurons Lynkuet helps to improve these vasomotor symptoms.

2. What you need to know before you take Lynkuet

Do not take Lynkuet if you

- are allergic to elinzanetant or any of the other ingredients of this medicine (listed in section 6)
- have ongoing severe liver problems
- are taking other medicines known as strong inhibitors of the CYP3A4 enzyme (such as cobicistat, clarithromycin, itraconazole, ritonavir). These medicines may cause Lynkuet to stay longer in your body, which may increase the risk of side effects.
- know or think that you might be pregnant.

Warnings and precautions

Before you start taking Lynkuet, your doctor may ask for your full medical history, including family history and you may have a blood sample taken to check your liver function.

If you experience any of the following effects, tell your doctor immediately: - tiredness, itching skin, yellowing of the skin and eyes, dark urine, light-coloured stools, feeling sick (nausea or vomiting), loss of appetite, and/or stomach ache. These symptoms may be signs of liver injury.

Talk to your doctor or pharmacist before taking Lynkuet, if you are:

- taking other medicines known as moderate inhibitors of the CYP3A4 enzyme (such as erythromycin, ciprofloxacin, fluconazole, verapamil). These medicines may cause Lynkuet to stay longer in your body, which may increase the risk of side effects.
- taking other medicines known as moderate to strong inducers of the CYP3A4 enzyme (such as rifampicin, carbamazepine, phenobarbital, St. John's Wort). These medicines may lower the levels of Lynkuet in your body.
- currently have or previously had breast cancer or another oestrogen-related cancer, especially for patients receiving anti-oestrogen treatment. During anti-oestrogen treatment, your doctor may decide not to prescribe this medicine to you.
- taking hormone replacement therapy with oestrogens (medicines used to treat oestrogen deficiency symptoms, not including topical vaginal oestrogen medicines). Your doctor may not prescribe this medicine to you.

Children and adolescents

This medicine is not for use in children and adolescents under 18 years.

Other medicines and Lynkuet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained with or without prescription, or over-the-counter medicines such as vitamins, dietary supplements or herbal medicines.

Certain medicines may influence how Lynkuet works. If you are on a moderate CYP3A4 inhibitor, then let your doctor know as they may need to prescribe you a lower dose of Lynkuet. Moderate CYP3A4 inhibitors may include medicines to:

- treat fungal or bacterial infections such as ciprofloxacin, erythromycin, fluconazole
- treat chest pains and high blood pressure such as verapamil

Lynkuet may influence how certain medicines work. These may include medicines to:

- prevent organ rejection after transplantation such as cyclosporine, tacrolimus
- treat long-term pain such as fentanyl

Lynkuet with food and drink

Do not eat grapefruit or drink grapefruit juice as long as you take this medicine.

This is because grapefruit is also known to be an inhibitor of the CYP3A4 enzyme and may cause Lynkuet to stay longer in your body. This may increase the risk of side effects.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or breast-feeding, or if you think you might be pregnant.

If you could get pregnant, you or your partner should use an effective birth control method to prevent pregnancy while you are taking this medicine. Ask your doctor about the best method of birth control for you.

If you get pregnant while taking this medicine, stop taking it and talk to your doctor.

Driving and using machines

If you feel tired, dizzy or sleepy while you are taking this medicine take extra care when driving or using machines.

Lynkuet contains sorbitol

This medicine contains 71 mg sorbitol in each capsule. Sorbitol is a source of fructose. Sorbitol may change how well other oral medicines work when you take them at the same time.

3. How to take Lynkuet

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

One dose is 2 capsules taken each day at bedtime.

Method of use

- Swallow the capsules whole with a glass of water. Do not cut, chew or crush the capsule due to its liquid formulation.
- Take Lynkuet orally once daily at bedtime with or without food.
- Do not take it with grapefruit juice or grapefruit. See “Lynkuet with food and drink” in section 2 for more information.

If you take more Lynkuet than you should

Taking too much Lynkuet may make side effects more likely or more severe. Talk to your doctor or pharmacist if you think you have taken too much of this medicine.

If you forget to take Lynkuet

If you miss a dose, take the next dose as planned on the following day at bedtime. Do not take more than 2 capsules on the same day to make up for a forgotten dose.

If you stop taking Lynkuet

Do not stop taking Lynkuet unless your doctor tells you to do so. If you want to stop taking this medicine before finishing treatment, talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)

- abdominal pain
- diarrhoea
- dizziness
- tiredness
- headache
- muscle spasms
- skin rash
- sleepiness

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lynkuet

- Keep this medicine out of the sight and reach of children.
- Do not store above 25 °C. Do not freeze.

- Do not use this medicine after the expiry date, which is stated on the carton and on each blister after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lynkuet contains

- The active substance is elinzanetant. Each soft capsule contains 60 mg of elinzanetant.
- The other ingredients are all-rac- α -tocopherol (E 307), caprylocaproyl macrogolglycerides, concentrated ammonia solution, gelatine, glycerol monocaprylate, glycerol monooleate, iron oxide red (E 172), iron oxide yellow (E 172), isopropyl alcohol, macrogol 400 (E 1521), polysorbate 80 (E 433), polyvinyl acetate phthalate, propylene glycol (E 1520), purified water, SDA 35A alcohol, sorbitol special-glycerin (E 420), titanium dioxide (E 171).

What Lynkuet looks like and contents of the pack

The soft capsules (capsules) are opaque red, oblong, and approximately 24 mm long and 11 mm in diameter. They are marked with a white printing of “EZLN60” on one side.

Lynkuet is available in cartons with foil blisters containing

- 24 (2 × 12) soft capsules
- 60 (5 × 12) soft capsules
- 180 (15 × 12) soft capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bayer plc
400 South Oak Way
Reading
RG2 6AD

Manufacturer

Catalent Germany Eberbach GmbH
Gammelsbacher Str. 2
69412 Eberbach
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder:

Bayer plc
Tel: 0118 206 3000

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