

PATIENT INFORMATION

LYNKUET® (lin kew et') (elinzanetant) capsules, for oral use

What is LYNKUET?

LYNKUET is a prescription medicine used to reduce moderate to severe hot flashes (also known as vasomotor symptoms) due to menopause. LYNKUET is not a hormone. Hot flashes are feelings of warmth in the face, neck, and chest, or sudden intense feelings of heat and sweating.

Do not take LYNKUET if you:

- are pregnant.

Before you use LYNKUET, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.
- have a history of seizures.
- are pregnant or planning to become pregnant. LYNKUET may harm your unborn baby. Women who can become pregnant should talk to their healthcare provider to exclude pregnancy before starting treatment with LYNKUET and use effective birth control during and for 2 weeks after stopping treatment.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LYNKUET may affect the way other medicines work, and other medicines may affect how LYNKUET works. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take LYNKUET?

- Take LYNKUET exactly as your healthcare provider tells you to take it.
- Take 2 LYNKUET capsules by mouth, with or without food, about the same time each day at bedtime.
- Swallow the LYNKUET capsules whole with water. Do not cut, crush, or chew capsules.
- If you miss a dose of LYNKUET at bedtime, take the next dose as scheduled the following day. Do not take more than 2 capsules on the same day to make up for a missed dose.
- If you take certain medicines, your healthcare provider may reduce your dose to 1 LYNKUET capsule. If so, partially peel back the foil of the blister card and leave the remaining capsule inside until your next dose.

What should I avoid while taking LYNKUET?

- Avoid eating grapefruit or drinking grapefruit juice during treatment with LYNKUET.
- LYNKUET may cause you to feel drowsy, if you experience this avoid driving and other hazardous activities until these effects go away. See "What are the possible side effects of LYNKUET?"

What are the possible side effects of LYNKUET?

LYNKUET can cause serious side effects, including:

- **Central nervous system (CNS) effects and daytime impairment.** LYNKUET can cause difficulty staying awake (somnolence) and other nervous system effects including fatigue, having a spinning feeling (vertigo), dizziness, and feeling faint (presyncope). If you experience these effects, you should not drive or do hazardous activities until these effects go away.
- **Increased liver blood test values.** LYNKUET may cause increased liver enzymes. Your healthcare provider will do a blood test to check your liver before you start and 3 months after taking LYNKUET. Stop taking LYNKUET and tell your healthcare provider right away if you have the following signs or symptoms that suggest liver problems:
 - feeling more tired than you do usually
 - decreased appetite
 - nausea
 - vomiting
 - itching
 - yellowing of the eyes or skin (jaundice)
 - pale feces
 - dark urine
 - pain in the stomach (abdomen)
- **Risk of pregnancy loss.** Taking LYNKUET while pregnant may cause loss of pregnancy or stillbirth. If you think you are pregnant, stop taking LYNKUET and tell your healthcare provider right away.
- **Risk of seizures in people with a history of seizures.** Seek medical attention right away if you have loss of consciousness or seizure.

Common side effects of LYNKUET include:

- headache
- fatigue
- dizziness
- feeling drowsy or sleepy
- stomach (abdominal) pain
- rash
- diarrhea
- muscle spasms

Tell your healthcare provider if you have any side effects that bother you or do not go away. These are not all the possible side effects of LYNKUET.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LYNKUET?

- Store LYNKUET at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep LYNKUET and all medicines out of the reach of children.**

General information about the safe and effective use of LYNKUET.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LYNKUET for a condition for which it was not prescribed. Do not give LYNKUET to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LYNKUET that is written for healthcare professionals.

What are the ingredients in LYNKUET?

Active ingredient: elinzanetant

Inactive ingredients: all-rac- α -Tocopherol, caprylocaproyl macrogolglycerides, glycerol monocaprylocaprate, glycerol mono-oleate, and polysorbate 80. The capsule is composed of edible ink, ferric oxide red, ferric oxide yellow, gelatin, sorbitol special-glycerin, and titanium dioxide.

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For more information, go to www.lynkuet.com or call 1-888-842-2937.