EMEA/H/C/006298

# Lynkuet (*elinzanetant*)

An overview of Lynkuet and why it is authorised in the EU

## What is Lynkuet and what is it used for?

Lynkuet is a medicine used to treat moderate-to-severe vasomotor symptoms (also referred to as hot flushes or night sweats) associated with menopause or caused by adjuvant endocrine therapy for breast cancer.

Adjuvant endocrine therapy is a treatment that blocks the effect of oestrogen, a female sex hormone, and is used after surgery or other cancer treatments to reduce the chance of breast cancer coming back. It may also be used to reduce the chance of breast cancer developing in women who have a high risk of breast cancer.

Lynkuet contains the active substance elinzanetant.

## How is Lynkuet used?

Lynkuet is available as capsules to be taken by mouth once a day at bedtime.

The medicine can only be obtained with a prescription. For more information about using Lynkuet, see the package leaflet or contact your doctor or pharmacist.

## How does Lynkuet work?

Before menopause or endocrine therapy, there is a balance between oestrogen and a protein called neurokinin B which regulates the brain's temperature control centre. During menopause or endocrine therapy, oestrogen levels decline, and this balance is disrupted, resulting in hot flushes.

The active substance in Lynkuet, elinzanetant, prevents neurokinin B from attaching to two of its targets (receptors) in the brain, thereby blocking its activity and reducing the number and intensity of hot flushes and night sweats.

## What benefits of Lynkuet have been shown in studies?

Two main studies involving a total of 796 women showed that Lynkuet is effective at reducing the frequency of hot flushes associated with menopause. After 4 weeks of treatment, the average number of daily moderate-to-severe hot flushes had dropped by around 8 in women taking Lynkuet compared

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

with around 5 in those taking placebo (a dummy treatment). After 12 weeks of treatment, the average number of daily moderate-to-severe hot flushes had dropped by around 9 in women taking Lynkuet compared with around 6 in those taking placebo. Women taking Lynkuet also reported a greater improvement in the severity of hot flushes, in sleep disturbance and in menopause-related quality of life compared with women taking placebo.

A supportive study involving 628 women found that the effect of Lynkuet in reducing the frequency of menopause-related hot flushes lasted at least 50 weeks.

A third main study involving 474 women found that Lynkuet was also effective at reducing the frequency of hot flushes caused by adjuvant endocrine therapy. After 4 weeks of treatment, the average number of daily moderate-to-severe hot flushes had dropped by around 6 in women taking Lynkuet compared with around 3 in those taking placebo. After 12 weeks of treatment, the number of daily moderate-to-severe hot flushes had dropped by around 8 in women taking Lynkuet compared with around 4 in those taking placebo. The effect of Lynkuet in reducing the frequency of hot flushes lasted at least 50 weeks. In this study, women taking Lynkuet also reported a greater improvement in sleep disturbance and menopause-related quality of life compared with those taking placebo.

## What are the risks associated with Lynkuet?

For the full list of side effects and restrictions with Lynkuet, see the package leaflet.

When used to treat hot flushes associated with menopause, the most common side effects with Lynkuet (which may affect up to 1 in 10 people) include headache and tiredness.

When used to treat hot flushes due to adjuvant endocrine therapy, the most common side effect with Lynkuet (which may affect more than 1 in 10 people) was tiredness. Other common side effects (which may affect up to 1 in 10 people) include sleepiness, diarrhoea, depression and muscle spasm.

Lynkuet should not be used during pregnancy or if pregnancy is suspected.

## Why is Lynkuet authorised in the EU?

Lynkuet was shown to be effective at reducing the frequency of hot flushes associated with menopause or caused by adjuvant endocrine therapy. Lynkuet was well tolerated and has an acceptable safety profile. The European Medicines Agency therefore decided that Lynkuet’s benefits are greater than its risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Lynkuet?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lynkuet have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Lynkuet are continuously monitored. Suspected side effects reported with Lynkuet are carefully evaluated and any necessary action taken to protect patients.

## Other information about Lynkuet

Lynkuet received a marketing authorisation valid throughout the EU on 17 November 2025.

Further information on Lynkuet can be found on the Agency’s website: ema.europa.eu/medicines/human/EPAR/lynkuet.

This overview was last updated in 11-2025.