

Summary report on authorisation dated 31 March 2026

Lynkuet[®] (active substance: elinzanetant)

Authorisation in Switzerland: 5 August 2025

Soft capsules for the treatment of moderate to severe hot flushes (vasomotor symptoms) in postmenopausal women

About the medicinal product

Lynkuet contains the active substance elinzanetant and is a non-hormonal medicinal product. It is used to treat moderate to severe hot flushes, otherwise known as vasomotor symptoms (VMS), in women after the menopause. VMS can occur because oestrogen levels decline after the menopause and the body's ability to regulate its own temperature is impaired.

Lynkuet was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic. The joint in-

itiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Lynkuet was submitted to the drug regulatory authorities in Australia, Canada, the United Kingdom and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessment of its foreign partner authorities in its authorisation decision.

Further details of the Access joint initiative are published on the Swissmedic website: [Access Consortium \(swissmedic.ch\)](https://www.swissmedic.ch).

Mode of action

The active substance elinzanetant acts on certain receptors in the brain that are involved in regulating body temperature and

sleep. By blocking certain messenger substances, Lynkuet can help reduce VMS.

Administration

Lynkuet is a prescription-only medicine.

Lynkuet is available as soft capsules. Each soft capsule contains 60 mg of the active substance elinzanetant. The recommended

daily dose is 120 mg, or two capsules, to be taken once a day before going to bed. The capsules should be swallowed whole, unchewed, with water.

Efficacy

The efficacy of Lynkuet was investigated in two studies involving 796 postmenopausal women experiencing moderate to severe VMS.

The women were treated with either Lynkuet or placebo (a dummy drug). The studies demonstrated that Lynkuet significantly reduced the frequency and severity of VMS

compared to placebo. This effect was sustained over the entire 26-week duration of the studies.

There was also evidence of an improvement in sleep quality.

The results for VMS were confirmed in a long-term study lasting 52 weeks.

Precautions, undesirable effects, & risks

Lynkuet must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects were headaches, fatigue, abdominal pain, diarrhoea, dizziness, muscle spasms and rash.

Lynkuet should not be used in patients who have severe hepatic impairment or who are taking certain medicinal products.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Menopausal hot flushes are a common phenomenon and affect many postmenopausal women. Lynkuet is a non-hormonal medicinal product that intervenes in temperature regulation in the brain.

The studies showed that Lynkuet reduced both the frequency and intensity of vasomotor symptoms in postmenopausal patients.

Taking all the risks and precautions into account, and based on the available data, the benefits of Lynkuet outweigh the risks. Swissmedic has therefore authorised the medicinal product Lynkuet containing the active substance elinzanetant in Switzerland for the treatment of moderate to severe hot flushes in postmenopausal women

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Lynkuet®](#)

Information for patients (package leaflet): [Information for patients Lynkuet®](#)

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.