Summary of the Risk Management Plan for LYNKUET®

Active substance: Elinzanetant

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LYNKUET®
(Elinzanetant)
Risk Management Plan

Summary of activities in the risk management plan

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks, as well as to prevent or minimise them.

The RMP summary of Lynkuet® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document, which is valid and relevant for the effective and safe use of Lynkuet® in Switzerland, is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Bayer (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Lynkuet®, hereinafter referred to as Lynkuet®.

Summary of Risk Management Plan for Lynkuet®

This is a summary of the risk management plan (RMP) for Lynkuet®. The RMP details important risks of Lynkuet®, how these risks can be minimised, and how more information will be obtained about Lynkuet®'s risks and uncertainties (missing information).

Lynkuet®'s Company Core Data Sheet (CCDS) and Company Core Patient Information (CCPI) documents describing the properties and the officially approved conditions of use of Lynkuet®, are providing essential information to healthcare professionals and patients on how Lynkuet® should be used.

At this point in time, no important risks and uncertainties are known for Lynkuet®.

Important new concerns will be included in updates of Lynkuet®'s RMP.

1. The medicine and what it is used for

Lynkuet® is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause (see CCDS/CCPI for the full prescribing information). It contains elinzanetant as the active substance and it is given orally once daily as soft capsule.

2. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

No important identified or potential risks are known for Lynkuet® at this point in time. All identified and potential risks are classified as non-important and are managed by the following *routine risk minimisation measures*:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and CCDS addressed to patients and healthcare professionals.
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly.
- The medicine's legal status — the medicine will be supplied to the patients via prescription only.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Benefit-Risk Evaluation Report/Periodic Safety Update Report assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

2.1 List of Important Risks and Missing Information

Important risks of Lynkuet® are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Lynkuet®. Potential risks are concerns for which an

association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

Table 1: Summary of safety concerns

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

2.2 Summary of Important Risks

Not applicable, as there are no important identified/potential risks or missing information included in the list of safety concerns.

3. Post-authorisation Development Plan

3.1 Studies which are conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligations of Lynkuet®.

3.2 Other Studies in Post-authorisation Development Plan

Not applicable.