Swiss Summary of the Risk Management Plan (RMP) for Lanadelumab (Takhzyro®)

Version 2.2, 30-May-2022
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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 risk as well as to prevent or minimize them.

The RMP summary of TAKHZYRO 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 TAKHZYRO in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Takeda Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of TAKHZYRO.

Summary of risk management plan for TAKHZYRO (Lanadelumab)

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

Takhzyro's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Takhzyro should be used.

This summary of the RMP for Takhzyro should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Takhzyro's RMP.

I. The medicine and what it is used for

Takhzyro is authorised for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients 12 years and older (see SmPC for the full indication). It contains lanadelumab as the active substance and it is given by subcutaneous route.

Further information about the evaluation of Takhzyro's benefits can be found in Takhzyro's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/takhzyro

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Takhzyro, together with measures to minimise such risks and the proposed studies for learning more about Takhzyro's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- 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 way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed including PSUR assessment so that immediate action can be taken as necessary.

These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Takhzyro is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Takhzyro are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Takhzyro. 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);

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• Use in Pregnancy and Lactation

II.B Summary of important risks

Missing Information: Use in Pregnancy and Lactation	
Evidence for linking the risk to the medicine	Not applicable.
Risk factors and risk groups	Not applicable.
Risk minimization measures	Routine risk minimisation measures: SmPC section 4.6 describe Pregnancy, Fertility and Lactation Additional risk minimisation measures: None.
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None.

II.C. Post-authorisation development plan

II.C.1. Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of lanadelumab.

II.C.2. Other studies in post-authorisation development plan

None.