VEOZA™ (FEZOLINETANT)

# *Public Risk Management Plan (RMP) Summary*

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

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# PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

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**Summary of risk management plan for fezolinetant**

This is a summary of the RMP for fezolinetant. The RMP details important risks of fezolinetant, how these risks can be minimized and how more information will be obtained about the risks for fezolinetant.

The fezolinetant SmPC gives essential information to healthcare professionals and patients on how fezolinetant should be used. A specific standardized follow-up questionnaire for all hepatic adverse events will help identify and characterize the safety profile in patients with moderate or severe hepatic impairment. This questionnaire will allow better documentation of the clinical course in all reported cases to recognize patterns and support causality assessment.

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

## I. THE MEDICINE AND WHAT IT IS USED FOR

VEOZA 45 mg tablets are authorized for the treatment of moderate to severe VMS associated with menopause. The tablets contain fezolinetant as the active substance and are taken orally.

## II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of fezolinetant, together with measures to minimize such risks and the proposed studies for learning more about the risks of fezolinetant, are outlined below.

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

- Specific information, such as warnings, precautions and advice on correct use, are in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed so that immediate action can be taken as necessary. A specific standardized follow-up questionnaire for all hepatic adverse events will help identify and characterize the safety profile in patients with moderate or severe hepatic impairment in case

fezolinetant was incidentally used in this patient population. This questionnaire will allow better documentation of the clinical course in all reported cases to recognize patterns and support causality assessment.

These measures constitute routine pharmacovigilance activities.

## II.A List of important risks and missing information

Important risks of fezolinetant are risks that need special risk management activities to further investigate or minimize 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 fezolinetant.
- Potential risks are concerns for which an association with the use of fezolinetant 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 fezolinetant 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 individuals with Child-Pugh Class B or C (moderate or severe) chronic hepatic impairment |

## II.B Summary of important risks

There are no important risks.

# II.C Postauthorization development plan

## II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of marketing authorization or specific obligation for fezolinetant.

## II.C.2 Other studies in postauthorization development plan

There are no studies required for fezolinetant.