Stemline®
A Menarini Group Company

ORSERDU® (Elacestrant)
Filmtabletten
Zul.-Nr. 69’417

Public Risk Management Plan (RMP) Summary

Version 1.0 (June 2024) based on EU-RMP V1.0 and the Switzerland Specific Annex V0.4

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 ORSERDU® 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 ORSERDU® in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Stemline Therapeutics Switzerland GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of ORSERDU®.

Summary of risk management plan (RMP) for ORSERDU (Elacestrant dihydrochloride)

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

ORSERDU's Arzneimittel information and its package leaflet give essential information to healthcare professionals and patients on how ORSERDU should be used.

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

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

I. The medicine and what it is used for:

ORSERDU is intended as monotherapy for the treatment of postmenopausal women, with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)- negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have progressed after at least one line of endocrine therapy combined with a CDK4/6 inhibitor.

It contains elacestrant dihydrochloride as the active substance and it is given orally with food.

Further information about the evaluation of ORSERDU's benefits can be found in ORSERDU's EPAR, including in its plain-language summary, available on the European Medicines Agency website.

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

Important risks of ORSERDU, together with measures to minimize such risks and the proposed studies for learning more about ORSERDU's risks, 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, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- The authorized pack size: the amount of medicine in a pack is chosen 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 minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report 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 ORSERDU is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of ORSERDU 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 to the use of ORSERDU. 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	Safety and efficacy in patients from racial and ethnic minority groups

II.B Summary of important risks

There are currently no important identified risks, important potential. There are, however, areas of missing information about ORSERDU. Risk with elacestrant, as outlined below.

Missing information: Safety and efficacy in patients from racial and ethnic minority groups	
Risk minimisation measures	Routine risk minimisation measures: • None Other routine risk minimisation beyond the Product Information: • None Legal status: • Prescription only medicine. Treatment to be initiated by experienced oncologists.
Additional pharmacovigilance activity	Post-marketing analysis (PMC 4394-2) in patients from racial and ethnic minority groups

II.C Post-authorization Development Plan

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

There is one safety and efficacy post-marketing study in patients from racial and ethnic minority groups.

Study short name:
Racial Diversity Analysis

Purpose of the study:
To further characterize the safety and efficacy of elacestrant in patients from racial and ethnic minority groups across clinical trials and other data sources.