

Summary of risk management plan for Orisild (Sildenafil citrate) Orion Corporation

Date: 05.01.2022, Version 2

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

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

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

I. The medicine and what it is used for

Orisild is authorised for treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III to improve exercise capacity, and treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension (see SmPC for the full indication). It contains sildenafil as the active substance and it is given by mouth.

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

Important risks of Orisild, together with measures to minimise such risks and the proposed studies for learning more about Orisild'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 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 Orisild is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Orisild 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 sildenafil. 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	<ul style="list-style-type: none">• Vaso-occlusive crisis in patients with sickle cell disease• Increased relative mortality in the paediatric population• Bleeding events (excluding epistaxis)
Important potential risks	<ul style="list-style-type: none">• Non-arteritic anterior ischaemic optic neuropathy (NAION)• Pulmonary haemorrhage in paediatric patients
Missing information	<ul style="list-style-type: none">• Long-term ocular safety• Safety in pregnancy• Long-term mortality

II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

There are no studies required for Orisild.