

## Part VI: Summary of the risk management plan

# Summary of risk management plan for Ruxolitinib Orion (ruxolitinib)

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

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

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

## I. The medicine and what it is used for

Ruxolitinib Orion is authorised for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (MF) (also known as chronic idiopathic MF), post-polycythemia vera (PV)-MF or post-essential thrombocythemia-MF. Ruxolitinib Orion also is indicated for the treatment of adult patients with PV who are resistant to or intolerant of hydroxyurea (HU). In addition, ruxolitinib is indicated for the treatment of patients with graft versus host disease (GvHD) in patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies. Ruxolitinib Orion contains ruxolitinib as the active ingredient and it is given by mouth.

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

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

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

Important risks of Ruxolitinib Orion 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 ruxolitinib. 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);

<b>List of important risks and missing information</b>	
Important identified risks	Serious infections
Important potential risks	Developmental toxicity
Missing information	Safety in pediatric patients $\geq$ 12 years (GvHD only)

## **II.B Summary of important risks**

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

## **II.C Post-authorisation development plan**

There are no studies required for Ruxolitinib Orion.