Part VI: Summary of the risk management plan

Summary of risk management plan for Ruxolitinib Vivanta/MSN tablets (Ruxolitinib)

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

Ruxolitinib´s Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Ruxolitinib should be used.

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

I. The medicine and what it is used for

Ruxolitinib is authorised for:

Myelofibrosis (MF)

Ruxolitinib is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

Polycythaemia vera (PV)

Ruxolitinib is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.

Graft versus host disease (GvHD)

Acute GvHD

Ruxolitinib is indicated for the treatment of adults and paediatric patients aged 28 days and older with acute graft versus host disease who have inadequate response to corticosteroids or other systemic therapies.

Chronic GvHD

Ruxolitinib is indicated for the treatment of adults and paediatric patients aged 6 months and older with chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies

It contains ruxolitinib as the active substance and are given by oral route of administration.

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

Important risks of Ruxolitinib, together with measures to minimise such 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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ruxolitinib 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 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);

List of important risks and missing information	
Important Identified risks	• Serious infections
Important Potential risks	• Developmental toxicity
Missing Information	• Long-term safety in the paediatric patients (GvHD only)

II.B Summary of important risks

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

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 obligations of Ruxolitinib.

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

There are no studies required for Ruxolitinib.