PART VI. SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for Ruxolitinib Accord 5 mg, 10 mg, 15 mg & 20 mg tablets

This is a summary of the risk management plan (RMP) for Ruxolitinib Accord 5 mg, 10 mg, 15 mg & 20 mg tablets. Throughout this summary, the product name to be referred as Ruxolitinib tablets. The RMP details important risks of Ruxolitinib tablets, how these risks can be minimized and how more information will be obtained about Ruxolitinib tablets risks and uncertainties (missing information).

Ruxolitinib tablets summary of product information (SmPC) and its package leaflet (PL) give essential information to health care professionals (HCPs) and patients on how Ruxolitinib tablets should be used.

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

I. The medicine and what is used for

Ruxolitinib tablets is authorized in the following indications:

- Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.
- Treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea..
- For the treatment of adults and pediatric patients aged 28 days and older with acute graft versus host disease (GvHD) and for the treatment of adults and pediatric patients aged 6 months and older with or chronic graft versus host disease, who have inadequate response to corticosteroids or other systemic therapies

It contains "ruxolitinib" as the active ingredient and it is given by oral route.

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

Important risks of Ruxolitinib tablets together with measures to minimize such risks and the proposed studies for learning more about Ruxolitinib tablets'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 HCPs;
- 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 minimize its risks.

Together, these measures constitute routine risk minimization measures. There are no additional risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, 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 Ruxolitinib tablets is not yet available, it is listed under 'missing information'.

II.A List of important risks and missing information

Important risks of Ruxolitinib tablets are risks that need special risk management activities to further investigate or minimize 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 tablets. 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 paediatric patients (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

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

There are no studies which are conditions of the marketing authorization or specific obligation of Ruxolitinib tablets.

II.C.2 Other studies in post-authorization development plan

There are no studies which are planned in the post-authorisation development plan for Ruxolitinib tablets.