Part VI: Summary of the Risk Management Plan

IS/H/0691/001-004/DC:

Summary of Risk Management Plan for Ruxolitinib Hexal 5 mg, 10 mg, 15 mg and 20 mg tablets (Ruxolitinib)

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

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

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

I. The Medicine and What It is used for

Ruxolitinib Hexal is authorised for:

- Myelofibrosis (MF)

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

- Polycythaemia vera (PV)

Ruxolitinib is indicated for the treatment of adult patients with PV 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 GvHD who have inadequate response to corticosteroids or other systemic therapies.

It contains Ruxolitinib as an active substance and it is given orally as tablets (5 mg, 10 mg, 15 mg and 20 mg tablets).

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

II.A List of Important Risks and Missing Information

Important risks of Ruxolitinib Hexal 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 Hexal. 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 risk	Serious infections
Important potential risk	Developmental toxicity
Missing information	Long-term safety in pediatric 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 Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ruxolitinib Hexal.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Ruxolitinib Hexal.

IS/H/0693/001-004/DC:

Summary of Risk Management Plan for Ruxolitinib Sandoz 5 mg, 10 mg, 15 mg and 20 mg tablets (Ruxolitinib)

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

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

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

I. The Medicine and What It is used for

Ruxolitinib Sandoz is authorised for:

- Myelofibrosis (MF)

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

- Polycythaemia vera (PV)

Ruxolitinib is indicated for the treatment of adult patients with PV 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 GvHD who have inadequate response to corticosteroids or other systemic therapies.

It contains Ruxolitinib as an active substance and it is given orally as tablets (5 mg, 10 mg, 15 mg and 20 mg tablets).

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

II.A List of Important Risks and Missing Information

Important risks of Ruxolitinib Sandoz 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 Sandoz. 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 risk	Serious infections
Important potential risk	Developmental toxicity
Missing information	Long-term safety in pediatric 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 Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ruxolitinib Sandoz.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Ruxolitinib Sandoz.

IS/H/0742/001-004/DC:
Summary of Risk Management Plan for Ycfelt 5 mg, 10 mg, 15 mg and 20 mg tablets (Ruxolitinib)

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

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

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

I. The Medicine and What It is used for

Ycfelt is authorised for:

- Myelofibrosis (MF)

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

- Polycythaemia vera (PV)

Ruxolitinib is indicated for the treatment of adult patients with PV 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 GvHD who have inadequate response to corticosteroids or other systemic therapies.

It contains Ruxolitinib as an active substance and it is given orally as tablets (5 mg, 10 mg, 15 mg and 20 mg tablets).

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

II.A List of Important Risks and Missing Information

Important risks of Ycfelt 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 Ycfelt. 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 pediatric 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 Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ycfelt.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Ycfelt.