Part VI: Summary of the risk management plan

Summary of risk management plan for Fingolimod Olpha (Fingolimod)

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

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

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

I. The medicine and what it is used for

Fingolimod Olpha is authorised for the treatment of as single disease modifying therapy in highly active relapsing remitting multiple sclerosis of adult and paediatric patients aged 10 years and older (see SmPC for the full indication). It contains fingolimod as the active substance and it is given orally.

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

Important risks of Fingolimod Olpha, together with measures to minimise such risks and the proposed studies for learning more about Fingolimod Olpha'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 the case of Fingolimod Olpha, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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 Fingolimod Olpha is not yet available, it is listed under «missing information» below.

II.A List of important risks and missing information

Important risks of Fingolimod Olpha 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 Fingolimod Olpha. 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	• Bradyarrhythmia (including conduction defects and bradycardia complicated by hypotension) occurring post-first dose • Liver transaminase elevation • Macular oedema • Opportunistic infections including PML, VZV, herpes viral infections other than VZV, fungal infection • Reproductive toxicity • Skin cancer (Basal cell carcinoma, Kaposi's sarcoma, Malignant melanoma, Merkel cell carcinoma, Squamous cell carcinoma) • Lymphoma
Important potential risks	• Other malignant neoplasms
Missing information	• Long-term use in paediatric patients, including impact on growth and development (including cognitive development)

II.B Summary of important risks

<u>Important identified risks</u>

Bradyarrhythmia (including conduction defects and bradycardia complicated by hypotension) occurring post-first dose	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.3, 4.4, 4.5 and 4.8 • Prescription medicine only Additional risk minimisation measures • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide

Liver transaminase elevation	
Risk minimisation measures	Routine risk minimisation measures:

	• Routine risk communication in SmPC sections 4.2, 4.3, 4.4, 4.8 and 5.2 • Prescription medicine only Additional risk minimisation measures • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide

Macular oedema	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.4 and 4.8 • Prescription medicine only Additional risk minimisation measures • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide

Opportunistic infections including PML, VZV, herpes viral infections other than VZV, fungal infection	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.3, 4.4 and 4.8 • Prescription medicine only Additional risk minimisation measures • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide

Reproductive toxicity	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC section 4.3, 4.4 and 4.6 • Prescription medicine only Additional risk minimisation measures

	• Pregnancy prevention • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide – Pregnancy-specific patient reminder card

Skin cancer (Basal cell carcinoma, Kaposi's sarcoma, Malignant melanoma, Merkel cell carcinoma, Squamous cell carcinoma)	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.4 and 4.8 • Prescription medicine only Additional risk minimisation measures • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide

Lymphoma	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.8 and 5.3 • Prescription medicine only Additional risk minimisation measures • No additional risk minimization measures

Important potential risks

Other malignant neoplasms	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC section 4.4 • Prescription medicine only Additional risk minimisation measures • No additional risk minimization measures

Missing information

Long-term use in paediatric patients, including impact on growth and development (including cognitive development)	
Risk minimisation measures	Routine risk minimisation measures: • Routine risk communication in SmPC sections 4.2 and 5.2 • Prescription medicine only Additional risk minimisation measures • Educational materials for physicians and patients: – Physician's checklist for adult and paediatric population – Patient/parent/caregiver guide

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 Fingolimod Olpha.

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

There are no studies required for Fingolimod Olpha.