Fingolimod 0.5 mg hard capsules

This is a summary of the risk management plan (RMP) for Fingolimod 0.5 mg hard capsules. The RMP details important risks of Fingolimod 0.5 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Fingolimod 0.5 mg hard capsules risks and uncertainties (missing information).

Fingolimod 0.5 mg hard capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fingolimod 0.5 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of RMP for Fingolimod 0.5 mg hard capsules.

I. The medicine and what it is used for

Fingolimod 0.5 mg hard capsules is indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of adult patients and paediatric patients aged 10 years and older:

- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (for exceptions and information about washout periods see SmPC sections 4.4 and 5.1).

or

- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

It contains Fingolimod as the active substance, 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 Fingolimod 0.5 mg hard capsules 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 the case of Fingolimod 0.5 mg hard capsules, these measures are supplemented with additional risk minimization 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 0.5 mg hard capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Fingolimod 0.5 mg hard capsules are risks that need special risk management activities to further investigate or minimise the risks, 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 0.5 mg hard capsules.

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 edema - 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) - Convulsions - Lymphoma
Important potential risks	- Other malignant neoplasms
Missing information	- Long-term use in pediatric patients, including impact on growth and development (including cognitive development)

II.B Summary of important risks

Important identified risk: Bradyarrhythmia (including conduction defects and bradycardia complicated by hypotension) occurring post-first dose	
Risk minimisation measures	<u>Routine risk minimisation measures</u> -SmPC Sections 4.2, 4.3, 4.4, 4,8 and 5.2 <u>Additional risk minimisation measures</u> Educational materials for physicians and patients: -Physician's checklist for adult and pediatric population -Patient/Parent/Caregiver´s guide
Important identified risk: Liver transaminase elevation	
Risk minimisation measures	<u>Routine risk minimisation measures</u> -SmPC Sections 4.2, 4.3, 4.4, 4.8 and 5.2 <u>Additional risk minimisation measures</u> Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide.

Important identified risk: Macular edema	
Risk minimisation measures	Routine risk minimisation measures -SmPC Sections 4.4 and 4.8 Additional risk minimisation measures Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide.
Important identified risk: Opportunistic infections including PML, VZV, herpes viral infections other than VZV, fungal infection	
Risk minimisation measures	Routine risk minimisation measures -SmPC Sections 4.3, 4.4 and 4.8 Additional risk minimisation measures Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide.
Important identified risk: Reproductive toxicity	
Risk minimisation measures	Routine risk minimisation measures -SmPC Sections 4.3, 4.4 and 4.6 Additional risk minimisation measures Pregnancy prevention Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide. -Pregnancy-specific patient reminder card
Important identified risk: Skin cancer (Basal cell carcinoma, Kaposi's sarcoma, Malignant melanoma, Merkel cell carcinoma, Squamous cell carcinoma)	
Risk minimisation measures	Routine risk minimisation measures -SmPC Sections 4.4 and 4.8 Additional risk minimisation measures Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide.
Important identified risk: Convulsions	
Risk minimisation measures	Routine risk minimisation measures

	-SmPC Sections 4.4 (pediatic patients) and 4.8 <u>Additional risk minimisation measures</u> Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide.
Missing information: Long-term use in pediatric patients, including impact on growth and development (including cognitive development)	
Risk minimisation measures	<u>Routine risk minimisation measures</u> -SmPC Sections 4.2 and 5.2 <u>Additional risk minimisation measures</u> Educational materials for physicians and patients: - Physician's checklist for adult and pediatric population - Patient / Parent / Caregiver's guide.

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 authorisation or specific obligation of Fingolimod 0.5 mg hard capsules.

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

There are no studies required for Fingolimod 0.5 mg hard capsules.