

1.8.2 Risk-management System

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 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) • 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**Important identified risks**

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

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Macular oedema	
	– 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

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Skin cancer (Basal cell carcinoma, Kaposi's sarcoma, Malignant melanoma, Merkel cell carcinoma, Squamous cell carcinoma)	
	• 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

Long-term use in paediatric patients, including impact on growth and development (including cognitive development)	
	– 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.