Part VI: Summary of the risk management plan

Summary of risk management plan for Teriflunomide (teriflunomide)

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

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

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

I. The medicine and what it is used for

Teriflunomide is authorised for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS) (see SmPC for the full indication). It contains teriflunomide 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 Teriflunomide, together with measures to minimise such risks and the proposed studies for learning more about Teriflunomide'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 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 Teriflunomide is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Teriflunomide 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 Teriflunomide. 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	Hepatic effects Hypertension Hematologic effects Infections Acute Pancreatitis
Important potential risks	Teratogenicity Serious opportunistic infections, including progressive multifocal leukoencephalopathy
Missing information	Long term safety in paediatric patients

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Safety concern	**Risk minimisation measures**
Hepatic effects	Routine risk communication SmPC: Sections 4.2, 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: Healthcare Professional and Patient/Carer Guide
Hypertension	Routine risk communication SmPC: Sections 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: Healthcare Professional and Patient/Carer Guide
Hematologic effects	Routine risk communication

Safety concern	Risk minimisation measures
	SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: Healthcare Professional and Patient/Carer Guide
Infections	Routine risk communication SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: Healthcare Professional and Patient/Carer Guide
Acute Pancreatitis	Routine risk communication SmPC: Sections 4.4 and 4.8 PIL: Section 2 and 4 Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: None
Teratogenicity	Routine risk communication SmPC: Sections 4.3 and 4.6 PIL: Section 2 Legal status: Restricted medical prescription in EU. Structured analysis of cases reporting pregnancy exposure to be submitted at dates corresponding to the PSUR submission dates for the reference product. Additional risk minimisation measures: Healthcare Professional and Patient/Carer Guide
Serious opportunistic infections, including progressive multifocal leukoencephalopathy	Routine risk communication SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: Healthcare Professional and Patient/Carer Guide

Safety concern	Risk minimisation measures
Long term safety in paediatric patients	Routine risk communication None. Legal status: Restricted medical prescription in EU. Additional risk minimisation measures: None

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 Teriflunomide.

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

There are no studies required for Teriflunomide.