Part VI: Summary of the risk management plan

Summary of risk management plan for Teriflunomide Tablets 14 mg (Teriflunomide).

This is a summary of the risk management plan (RMP) for Teriflunomide Film-coated tablets 14 mg. The RMP details important risks of Teriflunomide, how these risks can be minimised, and how more information will be obtained about Teriflunomide risks and uncertainties (missing information).

Teriflunomide Film-coated tablets 14 mg's Summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Teriflunomide Film-coated tablets 14 mg should be used.

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

I. The medicine and what it is used for

Teriflunomide Film-coated tablets are indicated for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS).

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 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 Teriflunomide Film-coated tablets 14 mg, 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 Teriflunomide Film-coated tablets 14 mg 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 administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is enough 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 PML
Missing information	• Long term safety in paediatric patients

PML: Progressive Multifocal Leukoencephalopathy.

II.B Summary of important risks

Important identified risk: Hepatic effects	
Risk minimisation measures	Routine risk minimization measures: SmPC: Sections 4.2, 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU) <u>Additional risk minimisation measures:</u> • HCP guide • Patient card

Important identified risk: Hypertension	
Risk minimisation measures	Routine risk minimization measures: SmPC: Sections 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU) Additional risk minimisation measures: • HCP guide • Patient card

Important identified risk: Hematologic effects	
Risk minimisation measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU) Additional risk minimisation measures: • HCP guide • Patient card

Important identified risk: Infections	
Risk minimisation measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU) Additional risk minimisation measures: • HCP guide • Patient card

Important potential risk: Teratogenicity	
Risk minimisation measures	Routine risk minimization measures: SmPC: Sections 4.3 and 4.6 PIL: Sections 2

Important potential risk: Teratogenicity	
	Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU) Additional risk minimisation measures: • HCP guide • Patient card

Important potential risk: Serious opportunistic infections, including PML	
Risk minimisation measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU) Additional risk minimisation measures: • HCP guide • Patient card

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.