Part VI: Summary of the risk management plan

Summary of risk management plan [Teriflunomide] 14mg film-coated tablets

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

[Teriflunomide] 14mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Teriflunomide] 14mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of [Teriflunomide] 14mg film-coated tablets RMP.

I. The medicine and what it is used for

[Teriflunomide] 14mg film-coated tablets is authorised for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS). 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] 14mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more [Teriflunomide] 14mg film-coated tablets, are outlined below.

Measures to minimise the risks for [Teriflunomide] 14mg film-coated tablets include:

- 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] 14mg film-coated tablets, 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 necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of [Teriflunomide] 14mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [Teriflunomide] 14mg film-coated tablets 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 of [Teriflunomide] 14mg film-coated tablets 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] 14mg film-coated tablets. 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	• None

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 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). *Additional risk minimization measures:* Educational Materials (HCP education/discussion guide and patient education card)
Important identified risk: **Hypertension**	
Risk minimisation measures	*Routine risk minimization measures:* SmPC: Sections 4.4 and 4.8 PIL: Sections 2 and 4 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). *Additional risk minimization measures:* Educational Material (HCP education/discussion guide and patient education 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 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). *Additional risk minimization measures:* Educational Material (HCP education/discussion guide and patient education 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 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). *Additional risk minimization measures:* Educational Material (HCP education/discussion guide and patient education card).
Important identified risk: **Acute pancreatitis**	
Risk minimisation measures	*Routine risk minimization measures:* SmPC: Sections 4.4 and 4.8 PIL: Section 2 and 4 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). *Additional risk minimization measures:* None
Important potential risk: **Teratogenicity**	
Risk minimisation measures	*Routine risk minimisation measures:* SmPC: Sections 4.3 and 4.6 PIL: Sections 2 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. 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: Educational Materials (HCP education/ discussion guide and Patient Education Card)
Important potential risk: **Serious opportunistic infections, including PML**	
Risk minimisation measures	*Routine risk minimisation measures:* SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Pack size: PVC/Aluminum/Polyamide blisters in cartons of 28 and 84 tablets. Not all pack sizes may be marketed. 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:* Educational Materials (HCP education/ discussion guide and Patient Education Card)

PML: Progressive Multifocal Leukoencephalopathy

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] 14mg film-coated tablets.

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

There are no studies required for [Teriflunomide] 14mg film-coated tablets.