13 Part VI: Summary of the risk management plan for Teriflunomide 14 mg, Film-coated Tablet

This is a summary of the risk management plan (RMP) for teriflunomide, 14 mg, film-coated tablet. The RMP details important risks of teriflunomide film-coated tablet, how these risks can be minimized, and how more information will be obtained about teriflunomide film-coated tablet's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of teriflunomide film-coated tablet's RMP.

13.1 Part VI: I. The medicine and what it is used for

Teriflunomide film-coated tablet is authorized for:

Teriflunomide is indicated for the treatment of adult patients and pediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS).

It contains teriflunomide as an active substance and is taken orally as film-coated tablet (14 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of teriflunomide film-coated tablet, together with measures to minimize such risks and the proposed studies for learning more about teriflunomide tablet's risks are outlined below.

Measures to minimize 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 minimize its risks.

Together, these measures constitute *routine risk minimization measures.*

In the case of teriflunomide film-coated tablet, 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 analyzed, including Periodic Safety Update Report (PSUR) assessment 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 tablet is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of teriflunomide film-coated tablet are risks that need special risk management activities to further investigate or minimize 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 film-coated tablet. 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).

Table 13-1 List of important risks and missing information

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 (PML)
Missing information	Long term safety in pediatric patients

13.2.2 Part VI – II.B: Summary of important risks

Table 13-2 Important identified risk: Hepatic effects

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.2, 4.3, 4.4 and 4.8 PL sections 2 and 4 Legal status: Prescription only **Additional risk minimization measures:** ▪ HCP Guide ▪ Patient Card

Table 13-3 Important identified risk: Hypertension

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.4 and 4.8 PL sections 2 and 4 Legal status: Prescription only **Additional risk minimization measures:** ▪ HCP Guide ▪ Patient Card

Table 13-4 Important identified risk: Hematologic effects

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.3, 4.4 and 4.8 PL sections 2 and 4 Legal status: Prescription only **Additional risk minimization measures:** ▪ HCP Guide ▪ Patient Card

Table 13-5 Important identified risk: Infections

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.3, 4.4 and 4.8 PL sections 2 and 4 Legal status: Prescription only **Additional risk minimization measures:** ▪ HCP Guide ▪ Patient Card

Table 13-6 Important potential risk: Teratogenicity

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.3 and 4.6 PL section 2 Legal status: Prescription only **Additional risk minimization measures:** ▪ HCP Guide ▪ Patient Card

Table 13-7 Important potential risk: Serious opportunistic infections, including PML

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.3, 4.4, and 4.8 PL sections 2 and 4 Legal status: Prescription only **Additional risk minimization measures:** ▪ HCP Guide ▪ Patient Card

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligations of teriflunomide film-coated tablet.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for teriflunomide film-coated tablet.