Part VI: Summary of the risk management plan

Summary of risk management plan for

Teriflunomide 14 mg film-coated tablets

(Teriflunomide)

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

Teriflunomide 14 mg film-coated tablets Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Teriflunomide 14 mg film-coated tablets should be used.

I. The medicine and what it is used for

Teriflunomide 14 mg film-coated tablets is indicated for the treatment for the treatment of adult patients with relapsing remitting forms of Multiple Sclerosis (MS) to reduce the frequency of clinical relapses and to delay the progression of physical disability (see SmPC for the full indication). It contains teriflunomide as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Teriflunomide 14 mg film-coated tablets, 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. prescription only medicine) 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, including 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 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 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.

Summary of safety concerns	
Important identified risks	• **Hepatic effects** • **Hypertension** • **Hematologic effects** • **Infections** • **Acute pancreatitis**
Important potential risks	• **Teratogenicity** • **Serious opportunistic infections, including PML**
Missing information	• **None**

II.B Summary of important risks

The safety information in the proposed Product Information (SPC and PIL) of Teriflunomide 14 mg film-coated tablets is aligned to the reference medicinal product Aubagio 14 mg film-coated tablets, Sanofi-Aventis[2].

<Important identified risk>: Hepatic effects	
Risk minimisation measures	<Routine risk minimisation measures> • SmPC: Sections 4.2, 4.3, 4.4 and 4.8 • PIL: Sections 2 and 4 • Prescription only medicine <Additional risk minimisation measures> Educational Materials: -HCP education/discussion guide and -patient education card

<Important identified risk>: Hypertension	
Risk minimisation measures	<Routine risk minimisation measures> • SmPC: Sections 4.4 and 4.8 • PIL: Sections 2 and 4 • Prescription only medicine <Additional risk minimisation measures> Educational Materials:

	-HCP education/discussion guide and -patient education card

<Important identified risk>: Hematologic effects	
Risk minimisation measures	<Routine risk minimisation measures> • SmPC: Sections 4.3, 4.4 and 4.8 • PIL: Sections 2 and 4 • Prescription only medicine <Additional risk minimisation measures> Educational Materials: -HCP education/discussion guide and -patient education card

<Important identified risk>: Infections	
Risk minimisation measures	<Routine risk minimisation measures> • SmPC: Sections 4.3, 4.4 and 4.8 • PIL: Sections 2 and 4 • Prescription only medicine <Additional risk minimisation measures> Educational Materials: -HCP education/discussion guide and -patient education card

<Important identified risk>: Acute pancreatitis	
Risk minimisation measures	<Routine risk minimisation measures> • SmPC: Sections 4.4 and 4.8 • PIL: Sections 2 and 4 • Prescription only medicine <Additional risk minimisation measures> None

<Important identified risk>: Teratogenicity	
Risk minimisation measures	<Routine risk minimisation measures> • SmPC: Sections 4.3 and 4.6 • PIL: Sections 2

	• Prescription only medicine <Additional risk minimisation measures> Educational Materials: -HCP education/discussion guide and -patient education card

<Important identified 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 • Prescription only medicine <Additional risk minimisation measures> Educational Materials: -HCP education/discussion guide and -patient education 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.