Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Teriflunomide Glenmark 14 mg Film-coated Tablets (Teriflunomide)

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

Teriflunomide Glenmark 14 mg film-coated tablets' Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to Healthcare Professionals (HCPs) and patients on how Teriflunomide Glenmark 14 mg film-coated tablets should be used.

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

I. The medicine and what it is used for

Teriflunomide Glenmark 14 mg film-coated tablets is indicated for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting Multiple Sclerosis. It contains teriflunomide as the active substance and it is taken by oral route.

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

Important risks of Teriflunomide Glenmark 14 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Teriflunomide Glenmark 14 mg film-coated tablets 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 PL and SmPC addressed to patients and HCPs;
- 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 Glenmark 14 mg film-coated tablets, 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, including Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A. List of important risks and missing information

Important risks of Teriflunomide Glenmark 14 mg 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 Glenmark 14 mg 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 risk(s)	• Hepatic effects • Hypertension • Hematologic effects • Infections • Acute Pancreatitis
Important potential risk(s)	• Teratogenicity • Serious opportunistic infections, including Progressive Multifocal Leukoencephalopathy (PML)
Missing information	• None

II.B. Summary of important risk

Important Identified Risk – Hepatic effects	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.2: Posology and method of administration • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take teriflunomide tablets • Section 4: Possible side effects <u>Additional risk minimisation measures:</u> Educational material for HCPs and patients which includes: • HCP Education/Discussion Guide

Important Identified Risk – Hepatic effects	
	• Patient Education Card

Important Identified Risk – Hypertension	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take teriflunomide tablets • Section 4: Possible side effects Additional risk minimisation measures Educational material for HCPs and patients which includes: • HCP Education/Discussion Guide • Patient Education Card

Important Identified Risk – Hematologic effects	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take teriflunomide tablets • Section 4: Possible side effects Additional risk minimisation measures: Educational material for HCPs and patients which includes: • HCP Education/Discussion Guide • Patient Education Card

Important Identified Risk – Infections	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take teriflunomide tablets • Section 4: Possible side effects Additional risk minimisation measures: Educational material for HCPs and patients which includes: • HCP Education/Discussion Guide • Patient Education Card

Important Potential Risk – Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.3: Contraindications • Section 4.6: Fertility, pregnancy and lactation **PL:** • Section 2: What you need to know before you take teriflunomide tablets Additional risk minimisation measures: Educational material for HCPs and patients which includes: • HCP Education/Discussion Guide • Patient Education Card

Important Potential Risk – Serious opportunistic infections, including PML	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL** • Section 2: What you need to know before you take teriflunomide tablets • Section 4: Possible side effects Additional risk minimisation measures: Educational material for HCPs and patients which includes: • HCP Education/Discussion Guide • 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 Glenmark 14 mg film-coated tablets.

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

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