SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Teriflunomide Mylan (teriflunomide)

This is a summary of the risk management plan (RMP) for Teriflunomide Mylan. The RMP details important risks of teriflunomide, how these risks can be minimised, and how more information will be obtained about teriflunomide's risks and uncertainties (missing information).

Teriflunomide Mylan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for Teriflunomide Mylan should be read in the context of all the information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Teriflunomide Mylan's RMP.

The Medicine and What it is Used For

Teriflunomide Mylan is authorised for the treatment of adult patients with relapsing remitting multiple sclerosis (MS). It contains teriflunomide as the active substance and it is given by oral route.

Further information about the evaluation of Teriflunomide Mylan's benefits can be found in Teriflunomide Mylan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/teriflunomide-mylan.

Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Teriflunomide Mylan 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 Mylan is not yet available, it is listed under 'missing information' below.

In the case of Teriflunomide Mylan, these routine measures are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

List of Important Risks and Missing Information

Important risks of Teriflunomide Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Mylan. 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/use in special patient populations etc.).

Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	• Hepatic effects (effects on the liver) • Hypertension (elevated blood pressure) • Hematologic Effects (effects on the blood) • Infections (infections) • Acute Pancreatitis (inflammation of the pancreas)
Important Potential Risks	• Teratogenicity (ability to cause defects in a developing fetus) • Serious opportunistic infections, including PML (infections due to reduction in immunity including a viral infection of the brain, PML)
Missing Information	• Long-term safety in paediatric patients (effect of long term use in children)

Summary of Important Risks

Hepatic effects

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.2, 4.3, 4.4 and 4.8 PL: Sections 2 and 4 Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: AE follow-up form for Drug induced liver injury

	Additional risk minimisation measures HCP guide and patient card

Hypertension

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.4 and 4.8 PL: Sections 2 and 4 **Additional risk minimisation measures** HCP guide and patient card

Hematologic effects

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.3, 4.4 and 4.8 PL: Sections 2 and 4 **Additional risk minimisation measures** HCP guide and patient card

Infections

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.3, 4.4 and 4.8 PL: Sections 2 and 4 **Additional risk minimisation measures** HCP guide and patient card

Acute Pancreatitis

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.4 and 4.8 PL: Sections 2 and 4 Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: AE follow-up form for Acute pancreatitis **Additional risk minimisation measures** Not applicable as there are no additional risk minimisation measures for this safety concern

Teratogenicity

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.3 and 4.6 PL: Section 2 Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Continuous collection and follow-up on cases of pregnancy with exposure to teriflunomide using specific follow-up forms; Regular submission of cumulative structured analyses of all collected pregnancy cases within PSURs **Additional risk minimisation measures** HCP guide and patient card

Serious opportunistic infections, including PML

Risk Minimisation Measures	**Routine risk minimisation measures** SmPC: Sections 4.3, 4.4 and 4.8 PL: Sections 2 and 4 Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: AE follow-up form for PML **Additional risk minimisation measures** HCP guide and patient card

Long-term safety in paediatric patients

Risk Minimisation Measures	**Routine risk minimisation measures** Not available **Additional risk minimisation measures** Not applicable as there are no additional risk minimisation measures for this safety concern

Post-Authorisation Development Plan

Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Teriflunomide Mylan.

Other Studies in Post-Authorisation Development Plan

There are no studies required for Teriflunomide Mylan.