Summary of risk management plan for Teriflunomide Accord 14 mg film-coated tablets (Teriflunomide)

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

Teriflunomide Accord 14 mg film-coated tablets prescribing information (SmPC/ PIL) give essential information to healthcare professionals and patients on how Teriflunomide Accord 14 mg film-coated tablets should be used.

Teriflunomide Accord 14 mg film-coated tablets should be read in the context of all this 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 Accord 14 mg film-coated tablets RMP.

I. The medicine and what it is used for

Teriflunomide Accord is indicated for the treatment of adult patients aged 10 years and older 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 Accord 14 mg film-coated tablets benefits can be found in Teriflunomide Accord 14 mg film-coated tablets 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-accord .

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

Important risks of Teriflunomide Accord 14 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Teriflunomide Accord 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 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment and signal management activity, 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 Accord 14 mg 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 Accord 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 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 Accord 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);

Important identified risks	• Hepatic effects • Hypertension • Hematologic effects • Infections • Acute Pancreatitis

Important potential risks	• Teratogenicity • Serious opportunistic infections, including PML
Missing Information	• Long term safety in pediatric patients

II.B Summary of important risks with additional risk minimization measures

The safety information in the proposed Product Information is aligned to the reference medicinal product Aubagio® (Teriflunomide).

Important Identified Risks: Hepatic Effects	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.4 and 4.8 of Teriflunomide Accord SmPC and corresponding sections of PIL have information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational Materials (HCP guide and Patient card)
Important Identified Risks: Hypertension	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.4 and 4.8 of Teriflunomide Accord SmPC and corresponding sections of PIL have information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational Materials (HCP guide and patient card)

Important Identified Risks: Haematologic effects	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.4 and 4.8 of Teriflunomide Accord SmPC and corresponding sections of PIL have information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational Materials (HCP guide and patient card)
Important Identified Risks: Infections	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.4 and 4.8 of Teriflunomide Accord SmPC and corresponding sections of PIL have information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational Materials (HCP guide and patient card)
Important Potential Risks: Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.4 and 4.8 of Teriflunomide Accord SmPC and corresponding sections of PIL have information on this safety concern. Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures:

	Educational Materials (HCP guide and patient card)
Important Potential Risks: **Serious opportunistic infections, including PML**	
Risk minimisation measures	Routine risk minimisation measures: Section 4.8 of Teriflunomide Accord SmPC and corresponding sections of PIL have information on this safety concern Other routine risk minimisation measures include the prescription only status of the product. Additional risk minimisation measures: Educational Materials (HCP guide and patient card)

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

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

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

There are no studies which are conditions of the marketing authorization or specific obligation of Teriflunomide Accord 14 mg film-coated tablets.