Part VI: Summary of the risk management plan

RMP Part VI is valid for all products in this RMP: Teriflunomide Devatis 7 mg & 14 mg film-coated tablets. .

Summary of risk management plan for Teriflunomide Devatis 7 mg & 14 mg film-coated tablets (Teriflunomide)

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

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

I. The medicine and what it is used for

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

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

Important risks of Teriflunomide Devatis, together with measures to minimise such risks and the proposed studies for learning more about Pomalidomide Devatis'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. with or without prescription) can help to minimise its risks.

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

In the case of Teriflunomide Devatis, 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 PSUR assessment 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 Devatis 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 Devatis. 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.

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 PML
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Hepatic effects	
Risk minimization measures	Routine risk minimization measures: SmPC**:** Sections 4.2, 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). Additional risk minimization measures: Educational Materials (Healthcare Professional education/discussion guide and patient education card).
Hypertension	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.4 and 4.8

	PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). <u>Additional risk minimization measures:</u> Educational Materials (Healthcare Professional education/discussion guide and patient education card).
Hematologic effects	
Risk minimization measures	<u>Routine risk minimization measures:</u> SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). <u>Additional risk minimization measures:</u> Educational Materials (Healthcare Professional education/discussion guide and patient education card).
Infections	
Risk minimization measures	<u>Routine risk minimization measures:</u> SmPC: Sections 4.3, 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). <u>Additional risk minimization measures:</u> Educational Materials (Healthcare Professional education/discussion guide and patient education card).
Acute pancreatitis	
Risk minimization measures	<u>Routine risk minimization measures:</u> SmPC: Sections 4.4 and 4.8 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by

	physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). Additional risk minimization measures: None
Teratogenicity	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.3 and 4.6 PIL: Section 2 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). Additional risk minimization measures: Educational Materials (Healthcare Professional education/discussion guide and patient education card).
Serious opportunistic infections, including PML	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.6 PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of Multiple Sclerosis (restricted medical prescription in European Union). Additional risk minimization measures: Educational Materials (Healthcare Professional 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 Devatis.

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

Theres are no studies required for Teriflunomide Devatis 7 mg & 14 mg film-coated tablets.