PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Dimethyl Fumarate Mylan (dimethyl fumarate)

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

Dimethyl Fumarate 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 Dimethyl Fumarate 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 Dimethyl Fumarate Mylan's RMP.

I. The medicine and what it is used for

Dimethyl Fumarate Mylan is authorised for the treatment of adult patients with relapsing remitting multiple sclerosis. It contains dimethyl fumarate as the active substance, and it is given by oral route.

Further information about the evaluation of Dimethyl Fumarate Mylan's benefits can be found in Dimethyl Fumarate 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/dimethyl-fumarate-mylan.

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

Important risks of Dimethyl Fumarate 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 Dimethyl Fumarate Mylan is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dimethyl Fumarate 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 Dimethyl Fumarate 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.);

Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	• PML • Decreases in leukocyte and lymphocyte counts • Drug-induced liver injury
Important potential risks	• Serious and opportunistic infections (other than PML and herpes zoster) • Malignancies • Effects on pregnancy outcome • Interaction with nephrotoxic medications leading to renal toxicity
Missing information	• Long term efficacy and safety • Safety profile in patients over the age of 55 years • Safety profile in patients with moderate to severe renal impairment • Safety profile in patients with hepatic impairment • Safety profile in patients with severe active GI disease

List of important risks and missing information	
	• Increased risk of infection in patients concomitantly taking anti-neoplastic or immunosuppressive therapies

II.B Summary of important risks

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

II.C Post-authorisation development plan

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

There are no studies which are conditions for the marketing authorisation or specific obligation of Dimethyl Fumarate Mylan.

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

There are no studies required for Dimethyl Fumarate Mylan.