Summary of risk management plan for Dimethyl Fumarate Polpharma (Dimethyl fumarate)

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

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

This summary of the RMP for Dimethyl Fumarate Polpharma 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 Dimethyl Fumarate Polpharma's RMP.

I. The medicine and what it is used for

Dimethyl Fumarate Polpharma is authorised for the treatment of adult patients with relapsing remitting multiple sclerosis (see SmPC for the full indication). It contains dimethyl fumarate as the active substance and it is given by mouth.

Further information about the evaluation of Dimethyl Fumarate Polpharma’s benefits can be found in Dimethyl Fumarate Polpharma’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-polpharm .

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

Important risks of Dimethyl Fumarate Polpharma, together with measures to minimise such risks and the proposed studies for learning more about Dimethyl Fumarate Polpharma'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 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*.

If important information that may affect the safe use of Dimethyl Fumarate Polpharma 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 Polpharma 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 Dimethyl Fumarate Polpharma. 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 risks	• Progressive Multifocal Leukoencephalopathy (PML) • Decreases in leukocyte and lymphocyte counts • Drug-induced liver injury
Important potential risks	• Serious and opportunistic infections (other than PML) • Malignancies • Effects on pregnancy outcome • Interaction with nephrotoxic medications leading to renal toxicity
Missing information	• Safety profile in patients over the age of 55 years • Safety profile in patients with renal impairment • Safety profile in patients with hepatic impairment • Safety profile in patients with severe active GI disease • Long term efficacy and safety • 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 of the marketing authorisation or specific obligation of Dimethyl Fumarate Polpharma.

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

There are no studies required for Dimethyl Fumarate Polpharma.