Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules (dimethyl fumarate)

This is a summary of the risk management plan (RMP) for Dimethyl fumarate Glenmark 120 mg gastro--resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules. The RMP details important risks of Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules, how these risks can be minimised, and how more information will be obtained about Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules risks and uncertainties (missing information).

Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules should be used.

I. The medicine and what it is used for

Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis.

It contains dimethyl fumarate as the active substance and it is given by oral route.

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

Important risks of Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules 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 PL 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 Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health

Authority, 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 Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules 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 Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules 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 Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules. 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 risk(s)	• Progressive Multifocal Leukoencephalopathy (PML) • Decreases in leukocyte and lymphocyte counts • Drug-induced liver injury
Important potential risk(s)	• 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 gastro-intestinal disease • Increased risk of infection in patients concomitantly taking anti-neoplastic or immunosuppressive therapies

II.B. Summary of important risk

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 Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules.

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

There are no studies required for Dimethyl fumarate Glenmark 120 mg gastro-resistant hard capsules and Dimethyl fumarate Glenmark 240 mg gastro-resistant hard capsules.