22 April 2024
EMA/145431/2024
Human Medicines Division

Authorisation details for Dimethyl fumarate Mylan

(Attachment to EPAR publication request) EMEA/H/C/006397

Active substance:	dimethyl fumarate
International Nonproprietary Name/Common Name (for vaccines only):	dimethyl fumarate
Pharmaco-therapeutic group (ATC Code [1]):	Immunosuppressants, Other immunosuppressants (L04AX07)
Therapeutic indication(s)[2]:	Dimethyl fumarate Mylan is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).
Authorised presentations:	See the Module "All authorised presentations"
Marketing Authorisation Holder:	Mylan Ireland Limited Unit 35/36 Grange Parade Baldoyle Industrial Estate Dublin 13 D13 R20R IRELAND
Date of issue of Marketing Authorisation valid throughout the European Union:	22 April 2024
Orphan medicinal product designation date:	Not applicable

(1) This shows the ATC Code(s) recorded in SIAMED for the first VALID presentation. The Pharmaco-therapeutic group should always refer to level 2 of the WHO classification.
(2) This shows the Therapeutic indication(s) recorded in SIAMED for the VALID presentations. The order of the indications will follow the order of the presentations.

NOTE: Please check the Therapeutic indication(s) carefully: for products where the indications are different between presentations, please ensure that the table shows the complete set of indications.