



Australian Government  
Department of Health  
Therapeutic Goods Administration

# Australian Public Assessment Report for Dimethyl Fumarate

Proprietary Product Name: Tecfidera

Sponsor: Biogen Idec Australia Pty Ltd

**October 2013**

**TGA** Health Safety  
Regulation

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## About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<http://www.tga.gov.au>>.

## About AusPARs

- An Australian Public Assessment Record (AusPAR) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve a prescription medicine submission.
- AusPARs are prepared and published by the TGA.
- An AusPAR is prepared for submissions that relate to new chemical entities, generic medicines, major variations, and extensions of indications.
- An AusPAR is a static document, in that it will provide information that relates to a submission at a particular point in time.
- A new AusPAR will be developed to reflect changes to indications and/or major variations to a prescription medicine subject to evaluation by the TGA.

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## List of abbreviations

| Abbreviation     | Meaning   |
|------------------|---|
| 9HPT             | Nine-Hole Peg Test                                  |
| AE               | adverse event                                       |
| ANCOVA           | analysis of covariance                              |
| AUC              | area under the curve                                |
| BG00012          | Tecfidera (dimethyl fumarate)                       |
| BID              | twice daily   |
| CI               | confidence interval                                 |
| C <sub>max</sub> | maximum plasma concentration                        |
| CNS              | central nervous system                              |
| CRF              | case report form                                    |
| CSR              | clinical study report                               |
| DMF              | dimethyl fumarate                                   |
| DMT              | disease modifying therapy                           |
| EDSS             | Expanded Disability Status Scale                    |
| EQ-5D            | European Quality of Life-5 Dimensions Health Survey |
| GA               | glatiramer acetate                                  |

| Abbreviation | Meaning   |
|--------------|---|
| Gd           | gadolinium  |
| IFN $\beta$  | interferon beta                                       |
| IM           | intramuscular   |
| INEC         | Independent Neurology Evaluation Committee            |
| ITT          | Intent-to-treat                                       |
| IV           | intravenous   |
| IVMP         | Intravenous methylprednisolone                        |
| MCS          | Mental Component Summary                              |
| MMF          | monomethyl fumarate                                   |
| MRI          | magnetic resonance imaging                            |
| MS           | multiple sclerosis                                    |
| MSFC         | Multiple Sclerosis Functional Composite               |
| MTR          | magnetization transfer ratio                          |
| Nrf2         | nuclear factor (erythroid-derived 2) related factor 2 |
| PASAT-3      | 3-Second Paced Auditory Serial Addition Test          |
| PBVC         | percent brain volume change                           |
| PCS          | Physical Component Summary                            |
| PD           | pharmacodynamics                                      |
| PK           | pharmacokinetics                                      |
| PPMS         | primary progressive multiple sclerosis                |
| PRMS         | progressive-relapsing multiple sclerosis              |
| QD           | once daily  |
| RRMS         | relapsing-remitting multiple sclerosis                |
| SAE          | serious adverse event                                 |
| SF-36        | Short Form-36® Health Survey                          |
| SC           | subcutaneous  |
| SIENA        | Structural Image Evaluation of Normalized Atrophy     |

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