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

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.

Contents

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_{max}	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 β	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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