

# CinnoTec

Dimethyl Fumarate

## Effective but Risky Treatment

**CinnoTec®** is a systemic Immunomodulator, indicated in relapsing form of multiple sclerosis. It is available in delayed release capsule **120mg** and **240mg** which is administered orally with or without food. Administering with food may decrease the incidence of flushing. The Initiate dose is 120mg twice daily for 7 days, then increase to the maintenance dose 240mg twice daily<sup>1</sup>.

### **WARNING: Progressive Multifocal Leukoencephalopathy (PML)<sup>2</sup>**

#### **There are three reported PML cases since 2014**

The **first** fatal case of (PML) reported to FDA occurred in a 54-year old woman with MS who received dimethyl fumarate 240mg three times daily for 4.5 years in the open-label extension study<sup>3-4</sup>. The Second and the Third non-fatal cases of PML in July and September 2015 have been reported in patients with prolonged lymphopenia<sup>5-6-7</sup>. PML is an opportunistic viral infection of the brain caused by the John Cunningham virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability.

### **Important Adverse Reactions**

- Anaphylaxis reaction
- Lymphopenia
- Infection
- Increased serum AST
- PML
- Flushing
- Skin rash
- Decrease WBC count

### **Reference:**

1. UpToDate, Version 21.2, dimethyl fumarate drug information.
2. [www.fda.gov/drugs/DrugSafety](http://www.fda.gov/drugs/DrugSafety).
3. Editorial letter, PML in a Patient with Lymphocytopenia Treated with Dimethyl Fumarate, NEJM 372;15, april 9, 2015.
4. [www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm424752.html](http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm424752.html)
5. <http://multiplesclerosis.net/news/tecfidera-linked-to-pml-once-again>.
6. <http://ms-people.com/forum/topic/22002-clinicspeak-third-pml-case-on-tecfidera/>
7. <http://www.bidnesstec.com/53119-biogen-inc-biib-tecfidera-pml-risk-unlikely-to-affect-sales-merrill-lynch/>