PART III: CONSUMER INFORMATION

TECFIDERA®
Dimethyl fumarate

This leaflet is part III of a three-part "Product Monograph" published when TECFIDERA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TECFIDERA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
TECFIDERA is a prescription medication to treat relapsing remitting multiple sclerosis (MS). TECFIDERA does not cure MS, but helps to reduce the number of flare-ups (relapses) that occur and slow the build-up of physical problems due to MS (disability progression).

What it does:
TECFIDERA may work by changing the way the body's immune system works, to help keep it from further damaging your brain and spinal cord.

When it should not be used:
Do not take TECFIDERA if you:
Have an allergy or are sensitive to dimethyl fumarate or any ingredients in this medicine.

TECFIDERA should not be used in children and adolescents under 18 years, because it has not been studied in MS patients younger than 18 years of age.

What the medicinal ingredient is:
Dimethyl fumarate.

What the nonmedicinal ingredients are:
Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, methacrylic acid copolymer (type A), methacrylic acid copolymer dispersion, microcrystalline cellulose, polysorbate 80, silicified microcrystalline cellulose, simethicone, sodium lauryl sulfate, talc, and triethyl citrate.

The capsule shell contains black iron oxide, FD&C Blue 1, gelatin, titanium dioxide, and yellow iron oxide.

What dosage forms it comes in:
Delayed-release capsules: 120 mg and 240 mg

WARNINGS AND PRECAUTIONS

BEFORE you use TECFIDERA talk to your doctor or pharmacist if:

- You have or have had low white blood cell counts (low lymphocytes). Low lymphocyte counts may be caused by another illness that affects the immune system (for example, immunodeficiency syndrome), bone marrow transplantation, or other treatments that can suppress the immune system.
- You have an infection.
- You have liver or kidney disease.
- You have a disease of the stomach or bowel.
- You are pregnant or planning to become pregnant.
- You are breast-feeding.

You should not receive certain types of vaccines (called "live attenuated vaccines") during treatment with TECFIDERA. Check with your doctor before receiving any vaccination during treatment or after stopping TECFIDERA.

INTERACTIONS WITH THIS MEDICATION

You should tell your doctor(s) if you are taking any other prescription or non-prescription medicines. This includes any vitamin or mineral supplements, or herbal products.

- **Fumaric acid.** Do not use TECFIDERA with other types of fumaric acid. Ask your doctor or pharmacist if you are not sure what other products may contain fumaric acids.
- **Medicines that affect the immune system** including some commonly used cancer treatments and other medicines used to treat MS, such as, natalizumab, fingolimod, or mitoxantrone. TECFIDERA should not be started while you are on other MS medications. If you stop taking one of these medicines to switch to TECFIDERA you may be required to wait before starting TECFIDERA. The amount of time you may need to wait will vary, depending on the treatment. Your doctor will know how long you may need to wait.
- **Medicines that can affect the kidneys**, such as antibiotics from the aminoglycoside class, non-steroidal anti-inflammatory drugs (NSAIDs), diuretics, or lithium. TECFIDERA has not been studied in patients who take these drugs regularly.
- **Vaccines.** During treatment with TECFIDERA, administration of vaccines containing live virus is not recommended.

PROPER USE OF THIS MEDICATION

Always follow your doctor's instructions for taking TECFIDERA. You should check with your doctor or pharmacist if you are not sure.

Swallow whole. Do not divide, crush, dissolve, suck, or chew the capsule.

TECFIDERA can be taken with or without food.

TECFIDERA capsules are packaged in a folding blister card inside a carton. Remove the capsules from the blister by pushing them through the foil.

Your doctor may reduce your dose if you have certain side effects. Do not reduce your dose unless your doctor tells you to

Usual adult dose:

Starting dose: one 120 mg capsule twice a day (one in the morning and one in the evening).
Starting total daily dose: 240 mg a day.
Take this starting dose for the first 7 days, and then take the regular dose.

Regular dose: one 240 mg capsule twice a day (one in the morning and one in the evening).
Regular total daily dose: 480 mg a day.

Overdose:

If you have taken more TECFIDERA than your doctor has recommended, contact a regional Poison Control Centre immediately and a health care practitioner, or go the nearest hospital emergency department even if there are no symptoms. Take the medication package with you when you go to the hospital.

Missed Dose:
If you forget or miss a dose, do not double your next dose.

You may take the missed dose if you leave at least 4 hours between the morning and evening doses, otherwise wait and take your next dose as planned.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:
Flushing and stomach upset. People are more likely to have these side effects when they first start taking TECFIDERA (mostly during the first month). Most people have mild to moderate symptoms and they tend to go away over time.

If you become flushed **and** get swelling of the face, lips, mouth or tongue, wheezing, difficulty breathing or shortness of breath, **stop taking TECFIDERA and seek emergency medical assistance.**

Signs of stomach upset may include:
- Diarrhea
- Nausea (feeling like you are going to be sick)
- Stomach pain or stomach cramps
- Vomiting (throwing up)
- Indigestion

Talk to your doctor about how to manage these side effects. Your doctor may reduce your dose. Do not reduce your dose unless your doctor tells you to.

Taking TECFIDERA with food may help manage these side effects. Your doctor may recommend taking an over-the-counter pain and fever reducer, such as aspirin, for a few days to manage signs of flushing.

TECFIDERA can cause abnormal blood and urine test results, including decreases in your white blood cell count. Your doctor will decide when to perform blood and urine tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical assistance
		Only if severe	In all cases	
Common	**Flushing** (symptoms of severe flushing may include general swelling, rash, itchiness)	✓		
	Gastrointestinal (GI) events (symptoms include diarrhea, nausea, stomach pain, vomiting, indigestion)	✓		
	Low levels of white blood cells (lymphocytes) (symptoms may include serious infections, e.g. pneumonia, or being more prone to infections)		✓	
	Proteins (albumin) in urine (symptoms may include swelling of the face or legs)		✓	
	Increased levels of liver enzymes (ALT, AST) in the blood (symptoms may include loss of appetite, fatigue, yellowing of the skin or eyes, or dark urine)		✓	
Un-common	**Allergic reaction** (symptoms include rash, itching, difficulty breathing, swelling of the face, lips, tongue or throat)			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical assistance
		Only if severe	In all cases	
Rare	**Progressive multifocal leukoencephal-opathy (PML), a rare brain infection.** (symptoms may include: progressive weakness on one side of the body, clumsiness of limbs, disturbance of vision, changes in thinking, memory and orientation, confusion, personality changes)			✓

This is not a complete list of side effects. For any unexpected effects while taking TECFIDERA, contact your doctor or pharmacist.

HOW TO STORE IT

Store TECFIDERA at room temperature (between 15 to 30°C). Protect TECFIDERA from light. Store the capsules in their original packaging. Do not take your medicine after the expiry date shown on the carton. Keep out of reach and sight of children.

Medicines should not be disposed of in waste water or household garbage. Ask your pharmacist how to dispose of medicines you no longer need.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting Biogen Canada Inc., at: 1-855-MSONE-00 (1-855-676-6300)

This leaflet was prepared by Biogen Canada Inc.

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