PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr TECFIDERA TM

Dimethyl Fumarate Delayed-Release Capsules

Read this carefully before you start taking **TECFIDERA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TECFIDERA**.

What is TECFIDERA used for?

TECFIDERA is used in adults to treat relapsing remitting multiple sclerosis (MS). TECFIDERA helps to:

- reduce the number of flare-ups (relapses) that occur, and
- delay physical problems due to MS (disability progression).

How does TECFIDERA work?

The exact way that TECFIDERA works is not known. However, TECFIDERA is thought to work by changing the way the body's immune system works, to help keep MS from further damaging your brain and spinal cord.

What are the ingredients in TECFIDERA?

Medicinal ingredient:	dimethyl fumarate
Non-medicinal ingredients:	black iron oxide, colloidal silicon dioxide, croscarmellose sodium, FD&C Blue 1, gelatin, magnesium stearate, methacrylic acid copolymer (type A), methacrylic acid copolymer dispersion, microcrystalline cellulose, polysorbate 80, silicified microcrystalline cellulose, simethicone, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate, and yellow iron oxide.

TECFIDERA comes in the following dosage forms:

Delayed-release capsules: 120 mg and 240 mg of dimethyl fumarate.

Do not use TECFIDERA if:

- you are allergic to dimethyl fumarate or to any other ingredients in TECFIDERA.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TECFIDERA. Talk about any health conditions or problems you may have, including if you:

- have or have had low white blood cell counts (low lymphocytes).
- have a weakened immune system (immunocompromised) due to diseases (immunodeficiency syndrome), medicines, or treatments that suppress the immune system (e.g., medicines used to treat cancer or bone marrow transplantation).
- have an infection.
- have a herpes zoster infection (shingles).

- have liver problems.
- have kidney problems.
- have gastrointestinal (GI) problems (e.g., stomach or bowel problems).
- are pregnant or planning to become pregnant.
- are breast-feeding or planning to breast-feed.
- are taking other medications known as fumaric acid derivatives.
- are taking certain medications that can affect your kidney function (nephrotoxic medications).
- are planning on getting certain types of vaccines known as live attenuated vaccines. Check with your healthcare professional before receiving any vaccination during treatment or after stopping TECFIDERA.

Other warnings you should know about:

Gastrointestinal (GI) problems: Treatment with TECFIDERA can cause GI problems, especially in the first month. Some symptoms of GI problems include nausea, vomiting, diarrhea, and abdominal pain. Most people have mild to moderate symptoms and they tend to go away over time. You should take TECFIDERA with food to help reduce the chances of GI problems. If this does not help, talk to your healthcare professional. They may also temporarily reduce your dose. Do not reduce your dose unless your healthcare professional tells you to.

Infections: If you have an infection before you start taking TECFIDERA, tell your healthcare professional. Any infection that you already have may get worse. Other infections, including shingles, have occurred when taking TECFIDERA. Infections could be serious and sometimes life-threatening.

- Before you start taking TECFIDERA, your healthcare professional will make sure you have enough white blood cells (lymphocytes) in your blood. This is because TECFIDERA may cause low white blood cell count (lymphopenia). Blood measurements are done throughout treatment and afterwards, to monitor your lymphocyte count.
- While you are taking TECFIDERA if you think you have an infection, have a fever, chills or feel like you have the flu, tell your healthcare professional right away. These may be the symptoms of infection.
- If you believe your MS is getting worse (e.g. weakness, clumsiness, or visual changes) or if you notice any new or unusual symptoms, talk to your healthcare professional as soon as possible. These may be the symptoms of a rare brain disorder caused by infection called progressive multifocal leukoencephalopathy (PML). Your healthcare professional might do an MRI scan to check for this condition. Your healthcare professional will decide whether you need to stop taking TECFIDERA.
- If you need to receive medications and treatments that suppress or change how the immune system works, talk to your healthcare professional about the potential increased risk of infections.

Liver problems: Treatment with TECFIDERA may cause liver problems, including increasing certain types of liver enzymes (i.e., liver transaminases) in your body. This usually happens during the first 6 months of treatment. Your healthcare professional will monitor your liver enzyme levels before, during, and after your treatment. They may stop your treatment if you have liver problems, or if liver problems are suspected.

Flushing: TECFIDERA may cause flushing, especially at the start of your treatment. Flushing can include hot flush, warmth, redness, itching, and burning sensation. Most people have mild to moderate

symptoms early in the treatment and they tend to go away over time. Your healthcare professional may temporarily reduce your dose or recommend taking an over-the-counter pain and fever medication, such as aspirin, for a few days 30 minutes before your TECFIDERA dose. Do not reduce your dose unless your healthcare professional tells you to.

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.**

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Monitoring and testing: Your healthcare professional will monitor and assess your health by doing various tests. These tests may be performed before, during, and after your treatment. This will tell your healthcare professional about your blood, urine, and liver. They will use this information to determine if TECFIDERA is right for you and how it is affecting you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TECFIDERA:

- **Fumaric acid.** TECFIDERA should not be used with other types of fumaric acid. Ask your healthcare professional if you are not sure what other products may contain fumaric acids or its derivatives.
- **Medicines that affect the immune system.** This can include some commonly used cancer treatments and other medicines used to treat MS, such as, beta-interferons, glatiramer acetate, 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 healthcare professional will know how long you may need to wait.
- **Medicines that can affect the kidneys.** This can include antibiotics from the aminoglycoside class, non-steroidal anti-inflammatory drugs (NSAIDs), diuretics, or lithium.
- **Vaccines.** If you need to receive a vaccine, talk to your healthcare professional first. The administration of vaccines containing live virus (attenuated vaccines) is not recommended.
- **Corticosteroids.** If you need to receive corticosteroids, talk to your healthcare professional about the potential increased risk of infections.
- **Acetylsalicylic acid.** Long-term use of acetylsalicylic acid (e.g., aspirin) is not recommended.

How to take TECFIDERA:

- Always follow your healthcare professional's instructions for taking TECFIDERA. You should check with your healthcare professional if you are not sure.
- **Swallow the whole TECFIDERA capsule**. Do not divide, crush, dissolve, suck, or chew the capsule.
- TECFIDERA can be taken with or without food. Taking TECFIDERA with food may help reduce the chances of certain side effects (flushing and gastrointestinal).
- 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 healthcare professional may reduce your dose if you have certain side effects. Do not reduce your dose unless your healthcare professional tells you to.

Usual dose:

Your healthcare professional will tell you how much and how often to take TECFIDERA each day. This will depend on your condition, other medications you are taking, and how you respond to the treatment. The usual starting and regular doses are as follows:

- **Starting dose:** One 120 mg capsule two times a day (one in the morning and one in the evening). For a total starting daily dose of 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 two times a day (one in the morning and one in the evening). For a total regular daily dose of 480 mg a day.

Overdose:

If you think you, or a person you are caring for, have taken too much TECFIDERA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or miss a dose, take it as soon as you remember if there is at least 4 hours between the morning and evening doses. If there is less than 4 hours, wait and take your next dose as planned. Do not try to make up for the missed dose by taking two doses at the same time.

What are possible side effects from using TECFIDERA?

These are not all the possible side effects you may have when taking TECFIDERA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Very Common - may affect more than 1 in 10 people
  - urinary tract infection
- Common - may affect up to 1 in 10 people
  - dry mouth
  - feeling hot
  - weight loss
  - ear infection
  - itchiness
  - skin rash
  - burning sensation
- Unknown frequency
  - runny nose
  - hair loss or thinning

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Flushing: hot flush, general swelling, rash, itchiness, warmth, redness, or burning sensation	✓		
Gastrointestinal (GI) problems: diarrhea, nausea, stomach pain, vomiting, indigestion	✓		
Infections: fever and chills, nausea, vomiting, diarrhea, or generally feeling unwell		✓	
COMMON			
Lymphopenia (low levels of white blood cells called lymphocytes): serious infections (e.g. pneumonia), or being more prone to getting infections		✓	
Proteinuria (excess proteins in the urine): frothy, foamy or bubbly urine; swelling of the face, hands, or legs; nausea; or muscle cramps at night		✓	
Liver problems (including increased levels of certain liver enzymes in the blood): loss of appetite, unusual tiredness, yellowing of the skin or eyes, dark urine, itching, nausea, or vomiting		✓	
Allergic reactions: rash, itching, difficulty breathing, difficulty swallowing, swelling of the face, lips, tongue or throat, wheezing, hives, rash			✓
RARE			
Progressive multifocal leukoencephalopathy (PML; a rare brain infection): progressive weakness on one side of the body, clumsiness of limbs, disturbance of vision, changes in thinking, memory and orientation, confusion, or personality changes			✓
UNKNOWN FREQUENCY			
Herpes zoster virus (shingles): skin rash of fluid-filled blisters, burning, itching or pain of the skin, typically on one side of the upper body or face, fever, weakness, or numbness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TECFIDERA at room temperature between 15°C 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.

If you want more information about TECFIDERA:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's (Biogen Canada Inc.) website www.biogen.ca/products/TECFIDERA_PM_EN, or by calling 1-855-MSONE-00 (1-855-676-6300).

This leaflet was prepared by Biogen Canada Inc.

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