Package leaflet: Information for the patient

Tecfidera 120 mg gastro-resistant hard capsules
Tecfidera 240 mg gastro-resistant hard capsules
dimethyl fumarate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tecfidera is and what it is used for

What Tecfidera is

Tecfidera is a medicine that contains the active substance **dimethyl fumarate**.

What Tecfidera is used for

Tecfidera is used to treat relapsing-remitting multiple sclerosis (MS).
MS is a long-term condition that affects the central nervous system (CNS), including the brain and the spinal cord. Relapsing-remitting MS is characterised by repeated attacks (relapses) of nervous system symptoms. Symptoms vary from patient to patient but typically include walking difficulties, feeling off balance and visual difficulties. These symptoms may disappear completely when the relapse is over, but some problems may remain.

How Tecfidera works

Tecfidera seems to work by stopping the body’s defence system from damaging your brain and spinal cord. This may also help to delay future worsening of your MS.

2. What you need to know before you take Tecfidera

Do not take Tecfidera:

- **if you are allergic to dimethyl fumarate** or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tecfidera may affect your **white blood cell counts**, your **kidneys** and **liver**. Before you start Tecfidera, your doctor will do a blood test to count the number of your white blood cells and will check that your kidneys and liver are working properly. Your doctor will test these periodically during treatment. If your number of white blood cells decreases during treatment, your doctor may consider interrupting your treatment

Talk to your doctor before taking Tecfidera if you have:
- severe **kidney** disease
- severe **liver** disease
- a disease of the **stomach** or **bowel**
- a serious **infection** (such as pneumonia)

Children and adolescents

Tecfidera should **not be used** in children and adolescents below 18 years old. The safety and effectiveness of Tecfidera in this age group are not known.

Other medicines and Tecfidera

Tell your doctor or pharmacist if you are taking, have recently taken or might take any medicines, in particular:
- medicines that contain **fumaric acid esters** (fumarates) used to treat psoriasis
- **medicines that affect the body's immune system** including **other medicines used to treat MS**, such as fingolimod, natalizumab or mitoxantrone or some commonly used **cancer** treatments
- **medicines that affect the kidneys including** some **antibiotics** (used to treat infections), "**water tablets**" (*diuretics*), **certain types of painkillers** (such as ibuprofen and other similar anti-inflammatories and medicines purchased without a doctor's prescription) and medicines that contain **lithium**
- **vaccinations** given while taking Tecfidera may be less effective than normal. Taking Tecfidera with certain types of vaccine (*live vaccines*) may cause you to get an infection and should therefore be avoided

Tecfidera with food and alcohol

Consumption of more than a small quantity (more than 50 ml) of strong alcoholic drinks (more than 30% alcohol by volume, e.g. spirits) should be avoided within an hour of taking Tecfidera, as alcohol can interact with this medicine. This could cause inflammation of the stomach (*gastritis*), especially in people already prone to gastritis.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not use Tecfidera if you are pregnant unless you have discussed this with your doctor.

Breast-feeding

It is not known whether the ingredients in Tecfidera pass into breast milk. Tecfidera is not to be used during breast-feeding. Your doctor will help you decide whether you should stop breast-feeding, or stop using Tecfidera. This involves balancing the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines

The effect of Tecfidera on the ability to drive or use machines is not known.Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely.

3. How to take Tecfidera

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Starting dose

120 mg twice a day.
Take this starting dose for the first 7 days, then take the regular dose.

Regular dose

240 mg twice a day.

Swallow each capsule whole, with some water. Do not divide, crush, dissolve, suck or chew the capsule as this may increase some side effects.

Take Tecfidera with food – it may help to reduce some of the very common side effects (listed in section 4).

If you take more Tecfidera than you should

If you have taken too many capsules, **talk to your doctor straight away**. You may experience side effects similar to those described below in section 4.

If you forget to take Tecfidera

If you forget or miss a dose, **do not take a double dose**.

You may take the missed dose if you leave at least 4 hours between the doses. Otherwise wait until your next planned dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious effects

Moderately low to very low lymphocyte counts - Lymphocyte counts (a type of white blood cell) may be decreased for a long period of time. Having a low white blood cell count for a long period of time can increase your risk of infection, including a risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to an MS relapse. Symptoms may include new or worsening weakness on one side of the body; clumsiness; changes in vision, thinking, or memory; or confusion or personality changes lasting for more than several days.

→ C**all your doctor straight away if you experience any of these symptoms**

Allergic reactions - these are uncommon and may affect *up to 1 in 100 people*

Reddening of the face or body (*flushing*) is a very common (*may affect more than 1 in 10 people*) side effect. However, if you become flushed **and** get any of these signs:

- swelling of the face, lips, mouth or tongue
- wheezing, difficulty breathing or shortness of breath

→ **Stop taking Tecfidera and call a doctor straight away**

Very common side effects

These may affect *more than 1 in 10 people:*
- reddening of the face or body feeling warm, hot, burning or itchy *(flushing)*
- loose stools *(diarrhoea)*
- feeling sick *(nausea)*
- stomach pain or stomach cramps

→ **Taking your medicine with food** can help to reduce the side effects above

Substances called ketones, which are naturally produced in the body, very commonly show up in urine tests while taking Tecfidera.

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.

Common side effects

These may affect *up to 1 in 10 people:*
- inflammation of the lining of the intestines (*gastroenteritis*)
- being sick *(vomiting)*
- indigestion (*dyspepsia*)
- inflammation of the lining of the stomach (*gastritis*)
- gastrointestinal disorder
- burning sensation
- hot flush, feeling hot
- itchy skin (*pruritus*)
- rash
- pink or red blotches on the skin (*erythema*)

Side effects which may show up in your blood or urine tests
- low levels of white blood cells (*lymphopenia, leucopenia*) in the blood. Reduced white blood cells could mean your body is less able to fight an infection. If you have a serious infection (such as pneumonia), talk to your doctor immediately
- proteins (*albumin*) in urine
- increase in levels of liver enzymes (*ALT, AST*) in the blood

Not known (frequency cannot be estimated from the available data)

- liver inflammation and increase in levels of liver enzymes (*ALT or AST in combination with bilirubin*)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tecfidera

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP".
The expiry date refers to the last day of that month.

Do not store above 30ºC.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tecfidera contains

The active substance is dimethyl fumarate.
Tecfidera 120 mg: Each capsule contains 120 mg of dimethyl fumarate.
Tecfidera 240 mg: Each capsule contains 240 mg of dimethyl fumarate.

The other ingredients are microcrystalline cellulose, croscarmellose sodium, talc, silica colloidal anhydrous, magnesium stearate, triethyl citrate, methacrylic acid – methyl methacrylate copolymer (1:1), methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30%, simeticone, sodium laurilsulfate , polysorbate 80, gelatin, titanium dioxide (E171), brilliant blue FCF (E133), yellow iron oxide (E172), shellac, potassium hydroxide and black iron oxide (E172).

What Tecfidera looks like and contents of the pack

Tecfidera 120 mg gastro-resistant hard capsules are green and white and printed with 'BG-12 120 mg' and are available in packs containing 14 capsules.

Tecfidera 240 mg gastro-resistant hard capsules are green and printed with 'BG-12 240 mg' and are available in packs containing 56 or 168 capsules.

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.