

Package leaflet: Information for the patient

Dimethyl Fumarate 120 mg and 240 mg hard gastro-resistant capsules

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 Dimethyl Fumarate is and what it is used for
2. What you need to know before you take Dimethyl Fumarate
3. How to take Dimethyl Fumarate
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1. What Dimethyl Fumarate is and what it is used for

What Dimethyl Fumarate is

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

What Dimethyl Fumarate is used for

Dimethyl Fumarate is used to treat relapsing-remitting multiple sclerosis (MS) in patients aged 13 years and older.

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 (e.g. blurred or double vision). These symptoms may disappear completely when the relapse is over, but some problems may remain.

How Dimethyl Fumarate works

Dimethyl Fumarate 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 Dimethyl Fumarate

Do not take Dimethyl Fumarate

- **if you are allergic to dimethyl fumarate** or any of the other ingredients of this medicine (listed in section 6).
- **if you are suspected to suffer from a rare brain infection called progressive multifocal leukoencephalopathy (PML) or if PML has been confirmed.**

Warnings and precautions

Dimethyl Fumarate may affect your **white blood cell counts**, your **kidneys** and **liver**. Before you start Dimethyl Fumarate, 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 additional tests or discontinue your treatment.

Talk to your doctor before taking Dimethyl Fumarate if you have:

- severe **kidney** disease
- severe **liver** disease
- a disease of the **stomach** or **bowel**
- a serious **infection** (such as pneumonia).

Herpes zoster (shingles) may occur with Dimethyl Fumarate treatment. In some cases, serious complications have occurred. **You should inform your doctor** immediately if you suspect you have any symptoms of shingles.

If you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms, talk to your doctor straight away because these may be the symptoms of a rare brain infection called PML. PML is a serious condition that may lead to severe disability or death.

A rare but serious kidney disorder (called Fanconi syndrome) has been reported with a medicine containing dimethyl fumarate, in combination with other fumaric acid esters, used to treat psoriasis (a skin disease). If you notice you are passing more urine, are thirstier and drinking more than normal, your muscles seem weaker, you break a bone, or just have aches and pains, talk to your doctor as soon as possible so that this can be investigated further.

Children and adolescents

Do not give this medicine to children below 10 years of age because no data are available in this age group.

Other medicines and Dimethyl Fumarate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular:

- medicines that contain **fumaric acid esters** (fumarates) used to treat psoriasis;
- **medicines that affect the body's immune system** including **chemotherapy**, **immunosuppressants**, or other **medicines used to treat MS**;
- **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**;
- taking this medicine with certain types of vaccines (*live vaccines*) may cause you to get an infection and should, therefore, be avoided. Your doctor will advise whether other types of vaccines (non-live vaccines) should be given.

Dimethyl Fumarate with alcohol

Consumption of more than a small amount (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 Dimethyl Fumarate, 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

There is limited information about the effects of this medicine on the unborn child if used during pregnancy. Do not use Dimethyl Fumarate if you are pregnant unless you have discussed this with your doctor and this medicine is clearly necessary for you.

Breast-feeding

It is not known whether the active substance of this medicine passes into breast milk. Your doctor will advise whether you should stop breast-feeding or stop using Dimethyl Fumarate. This involves balancing the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines

This medicine is not expected to affect your ability to drive and use machines.

3. How to take Dimethyl Fumarate

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.

Dimethyl Fumarate is for oral use.

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

If you take more Dimethyl Fumarate 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 Dimethyl Fumarate

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 side effects

Dimethyl Fumarate may lower lymphocyte counts (a type of white blood cell). Having a low white blood cell count can increase your risk of infection, including the risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML). PML may lead to severe disability or death. PML has occurred after 1 to 5 years of treatment and so your physician should continue to monitor your white blood cells throughout your treatment, and you should remain observant of any potential symptoms of PML as described below. The risk of PML may be higher if you have previously taken a medicine impairing the functionality of your body's immune system.

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, or speech and communication difficulties lasting for more than several days. Therefore, if you believe your MS is getting worse or if you notice any new symptoms while you are on Dimethyl Fumarate treatment, it is very important that you speak to your doctor as soon as possible. Also speak with your partner or caregivers and inform them about your treatment. Symptoms might arise that you might not become aware of by yourself.

→ **Call your doctor straight away if you experience any of these symptoms.**

Severe allergic reactions

The frequency of severe allergic reactions cannot be estimated from the available data (not known).

Reddening of the face or body (*flushing*) is a very common side effect. However, should flushing be accompanied by a red rash or hives **and** you get any of these symptoms:

- swelling of the face, lips, mouth or tongue (*angioedema*)
- wheezing, difficulty breathing or shortness of breath (*dyspnoea, hypoxia*)
- dizziness or loss of consciousness (*hypotension*).

then this may represent a severe allergic reaction (*anaphylaxis*).

→ **Stop taking Dimethyl Fumarate and call a doctor straight away.**

Other side effects

Very common (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 dimethyl fumarate.

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 (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*)
- hair loss (alopecia).

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.

Uncommon (may affect up to 1 in 100 people):

- allergic reactions (*hypersensitivity*)
- reduction in blood platelets.

Rare (may affect up to 1 in 1 000 people):

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

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

- herpes zoster (*shingles*) with symptoms such as blisters, burning, itching or pain of the skin, typically on one side of the upper body or the face, and other symptoms, like fever and weakness in the early stages of infection, followed by numbness, itching or red patches with severe pain
- runny nose (*rhinorrhoea*).

Children (13 years of age and above) and adolescents

The side effects listed above also apply to children and adolescents.

Some side effects were reported more frequently in children and adolescents than in adults, e.g. headache, stomach pain or stomach cramps, being sick (*vomiting*), throat pain, cough, and painful menstrual periods.

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 the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dimethyl Fumarate

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 blister and the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. 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 throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dimethyl Fumarate contains

The active substance is dimethyl fumarate.

Dimethyl Fumarate 120 mg hard gastro-resistant capsules

Each gastro-resistant hard capsule contains 120 mg of dimethyl fumarate.

Dimethyl Fumarate 240 mg hard gastro-resistant capsules

Each gastro-resistant hard capsule contains 240 mg of dimethyl fumarate.

The other ingredients are:

- Capsule content: cellulose, microcrystalline, crospovidone, talc, povidone, silica colloidal anhydrous, magnesium stearate, triethyl citrate, methacrylic acid/ethylacrylate copolymer (1:1), hypromellose, titanium dioxide (E 171) and triacetin.
- Capsule shell: gelatin, titanium dioxide (E 171), brilliant blue FCF (E 133) and yellow iron oxide (E 172).
- Capsule printing ink: shellac, potassium hydroxide, propylene glycol (E 1520), black iron oxide (E 172) and strong ammonia solution.

What Dimethyl Fumarate looks like and contents of the pack

Dimethyl Fumarate 120 mg gastro-resistant hard capsules (gastro-resistant capsules): green cap and white body, capsule shell of 21.4 mm, imprinted in black ink with “DMF 120” on the body containing white to off-white minitabets.

Dimethyl Fumarate 240 mg hard gastro-resistant capsules (gastro-resistant capsules): green cap and body, capsule shell of 23.2 mm, imprinted in black ink with “DMF 240” on the body containing white to off-white minitabets.

oPA/Alu/PVC//Alu blisters or oPA/Alu/PVC//Alu perforated unit dose blisters.

Dimethyl Fumarate 120 mg hard gastro-resistant capsules

Pack sizes:

14 capsules in blisters or 14 x 1 capsules in perforated unit dose blisters.

Dimethyl Fumarate 240 mg hard gastro-resistant capsules

Pack sizes:

56, 168 or 196 capsules in blisters or 56 x 1, 168 x 1 or 196 x 1 capsules in perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Norton Waterford,
T/A IVAX Pharmaceuticals Ireland
Unit 301, IDA Industrial Park,
Waterford,
Ireland

Manufacturer

Pharmadox Healthcare Limited, KW20A Kordin Industrial Park, Paola, PLA 3000, Malta

Adalvo Limited, Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, SGN 3000, Malta

KeVaRo GROUP Ltd, 9 Tzaritza Elenora Str., office 23, Sofia, 1618, Bulgaria

Teva Operations Poland Sp. z.o.o., ul. Mogilska 80, Kraków, 31-546, Poland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Iceland	Dimethyl fumarate Teva
Austria	Dimethylfumarat !@ctavis 120 mg magensaftresistente Hartkapseln Dimethylfumarat !@ctavis 240 mg magensaftresistente Hartkapseln
Belgium	Dimethyl Fumarate rtp 120 mg harde maagsapresistente capsules Dimethyl Fumarate rtp 240 mg harde maagsapresistente capsules
Cyprus	Dimethyl fumarate/Teva
Czechia	Dimethyl fumarát Teva GmbH
Germany	Dimethylfumarat-ratiopharm 120 mg magensaftresistente Hartkapseln Dimethylfumarat-ratiopharm 240 mg magensaftresistente Hartkapseln
Denmark	Dimethyl fumarate Teva
Estonia	Dimethyl fumarate Teva
Greece	Dimethyl fumarate/Teva
Spain	Fumarato de dimetilo Teva 120 mg cápsulas duras gastrorresistentes EFG Fumarato de dimetilo Teva 240 mg cápsulas duras gastrorresistentes EFG
Finland	Dimethyl fumarate Teva GmbH 120 mg enterokapseli, kova Dimethyl fumarate Teva GmbH 240 mg enterokapseli, kova
France	DIMETHYL FUMARATE TEVA 120 mg, gélule gastro-résistante DIMETHYL FUMARATE TEVA 240 mg, gélule gastro-résistante
Croatia	Dimetilfumarat Teva 120 mg,240 mg tvrde želučanootporne capsule
Hungary	Dimetil-fumarát Teva GmbH 120 mg gyomornedv-ellenálló kemény kapszula Dimetil-fumarát Teva GmbH 240 mg gyomornedv-ellenálló kemény kapszula
Ireland	Dimethyl Fumarate 120 mg and 240 mg hard gastro-resistant capsules
Italy	DIMETILFUMARATO TEVA GENERICS
Latvia	Dimethyl fumarate Teva 120 mg zarnās šķīstošās cietās kapsulas Dimethyl fumarate Teva 240 mg zarnās šķīstošās cietās kapsulas
Lithuania	Dimethyl fumarate Teva 120 mg skrandyje neirios kietosios kapsulės Dimethyl fumarate Teva 240 mg skrandyje neirios kietosios kapsulės
Netherlands	Dimethylfumaaraat Teva 120 mg, harde maagsapresistente capsules Dimethylfumaaraat Teva 240 mg, harde maagsapresistente capsules
Norway	Dimethyl fumarate Teva

Poland	Dimethyl fumarate Teva GmbH
Portugal	Fumarato de dimetilo Teva
Sweden	Dimethyl fumarate Teva
Slovenia	Dimetilfumarat Teva 120 mg, 240 mg gastrorezistentne trde kapsule
Slovakia	Dimethyl fumarát Teva GmbH 120 mg tvrdé gastrorezistentné kapsuly Dimethyl fumarát Teva GmbH 240 mg tvrdé gastrorezistentné kapsuly

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