PACKAGE LEAFLET
Package leaflet: Information for the patient

Dimethylfumaraat SDZ 120 mg, harde maagsapresistente capsules
Dimethylfumaraat SDZ 240 mg, harde maagsapresistente 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 [Nationally completed name] is and what it is used for

What [Nationally completed name] is

[Nationally completed name] is a medicine that contains the active substance **dimethyl fumarate**.

What [Nationally completed name] is used for

[Nationally completed name] 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 [Nationally completed name] works

[Nationally completed name] 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 [Nationally completed name]

Do not take [Nationally completed name]

- **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

[Nationally completed name] may affect your **white blood cell counts**, your **kidneys** and **liver**. Before you start [Nationally completed name], 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 [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name]

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 [Nationally completed name] 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.

[Nationally completed name] 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 [Nationally completed name], 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 [Nationally completed name] 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 [Nationally completed name] passes into breast milk. Your doctor will advise whether you should stop breast-feeding, or stop using [Nationally completed name]. This involves balancing the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines

[Nationally completed name] is not expected to affect your ability to drive and use machines.

3. How to take [Nationally completed name]

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.

[Nationally completed name] 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.

The bottles contain a desiccant. Do not swallow the desiccant canister.

Take [Nationally completed name] with food – it may help to reduce some of the very common side effects (listed in section 4).

If you take more [Nationally completed name] 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 [Nationally completed name]

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

[Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name].

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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, blister or bottle after "EXP". The expiry date refers to the last day of that month.

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 [Nationally completed name] contains

The active substance is dimethyl fumarate.
[Nationally completed name] 120 mg: Each capsule contains 120 mg of dimethyl fumarate.
[Nationally completed name] 240 mg: Each capsule contains 240 mg of dimethyl fumarate.

The other ingredients are:
capsule content: microcrystalline cellulose, povidone-K30, crospovidone, silica colloidal anhydrous, magnesium stearate, hypromellose, triacetin, talc, methacrylic acid-ethylacrylate co polymer (1:1), titanium dioxide (E 171), triethyl citrate.

Capsule shell: gelatin, titanium dioxide (E 171), yellow iron oxide (E 172), brilliant blue FCF (E 133); Printing ink:shellac, propylene glycol (E 1520), Strong Ammonia Solution (E 527), Potassium Hydroxide, black iron oxide (E 172).

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] 120 mg gastro-resistant hard capsules
Green opaque cap and white opaque body, capsule shell size No. 0, length 21.4 mm, imprinted in black ink with “DMF 120” on the body containing white to off-white minitablets.

[Nationally completed name] 240 mg gastro-resistant hard capsule
Green opaque cap and body, capsule shell size No. 00, length 23.2 mm, imprinted in black ink with “DMF 240” on the body containing white to off-white minitablets.

[Nationally completed name] 120 mg gastro-resistant hard capsules
OPA/Al/PVC //Al blisters or perforated unit dose blisters
Pack sizes: 14 or 14 x 1 gastro-resistant hard capsules

HDPE bottles with PP/HDPE screw cap with seal and silica gel desiccant canister
Pack size: 100 gastro-resistant hard capsules

[Nationally completed name] 240 mg gastro-resistant hard capsule
OPA/Al/PVC //Al blisters or perforated unit dose blisters
Pack sizes: 56, 56 x 1, 168, 168 x 1, and 196 gastro-resistant hard capsules

HDPE bottles with PP/HDPE screw cap with seal and silica gel desiccant canister
Pack size:100 gastro-resistant hard capsules

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Lek Pharmaceuticals d.d.
Verovskova Ulica 57
1526 Ljubljana
Slovenië

Pharmadox Healthcare Limited
Kw20a Kordin Industrial Estate
PLA 3000 Paola
Malta

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

KeVaRo Group d.d.
9. Tsaritsa Eleonora Str.
Office 23
1618 Sofia
Bulgarije

In het register ingeschreven onder:
RVG 129796 - Dimethylfumaraat SDZ 120 mg, harde maagsapresistente capsules
RVG 129797 - Dimethylfumaraat SDZ 240 mg, harde maagsapresistente capsules

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte en in het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:

Oosenrijk	Dimethylfumarat 1A Pharma GmbH 120, 240 mg - magensaftresistente Hartkapseln
Cyprus	Dimethyl fumarate/sandoz 120, 240 mg γαστροανθεκτικο καψακιο, σκληρο
Denemarken	Dimethyl fumarate Hexal
Finland	Dimethyl fumarate Hexal 120, 240 mg enterokapseli, kova
Duitsland	Dimethylfumarat - 1 A Pharma 120, 240 mg magensaftresistente Hartkapseln
Griekendland	Dimethyl fumarate/sandoz 120, 240 mg γαστροανθεκτικά σκληρά καψάκια
Hongarije	Dimetil-fumarát 1 A Pharma 120, 240 mg gyomornedv-ellenálló kemény kapszula
IJsland	Dimethyl fumarate Hexal
Ierland	Dimethyl fumarate Rowex 240 mg gastro-resistant hard capsules
Malta	Dimethyl fumarate sandoz 120mg gastro-resistant hard capsules
Nederland	Dimethylfumaraat SDZ 120, 240 mg, harde maagsapresistente capsules
Noorwegen	Dimethyl fumarate Hexal 120, 240 mg enterokapsel, hard
Portugal	Fumarato de dimetilo Sandoz
Zweden	Dimethyl fumarate Hexal

Deze bijsluiter is voor het laatst goedgekeurd in april 2026.