

PACKAGE LEAFLET

Package leaflet: Information for the patient

Dimethyl fumarate Rowex 120 mg hard gastro-resistant capsules Dimethyl fumarate Rowex 240 mg hard gastro-resistant 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 Dimethyl fumarate Rowex is and what it is used for
2. What you need to know before you take Dimethyl fumarate Rowex
3. How to take Dimethyl fumarate Rowex
4. Possible side effects
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1. What Dimethyl fumarate Rowex is and what it is used for

What Dimethyl fumarate Rowex is

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

What Dimethyl fumarate Rowex is used for

Dimethyl fumarate Rowex 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 Rowex works

Dimethyl fumarate Rowex 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 Rowex

Do not take Dimethyl fumarate Rowex

- **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 Rowex may affect your **white blood cell counts**, your **kidneys** and **liver**. Before you start Dimethyl fumarate Rowex, 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 Rowex 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 Rowex 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 Rowex

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 Dimethyl fumarate Rowex 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 Rowex 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 Rowex, 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 Rowex 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 Dimethyl fumarate Rowex passes into breast milk. Your doctor will advise whether you should stop breast-feeding, or stop using Dimethyl fumarate Rowex. This involves balancing the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines

Dimethyl fumarate Rowex is not expected to affect your ability to drive and use machines.

Dimethyl fumarate Rowex contains sodium

Dimethyl fumarate Rowex contains less than 1 mmol sodium (23 mg) per gastro-resistant hard capsule, that is to say essentially 'sodium-free'.

3. How to take Dimethyl fumarate Rowex

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

If you take more Dimethyl fumarate Rowex 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 Rowex

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 Rowex 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 Rowex 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 Rowex 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 Rowex.

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: 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 Rowex

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.

Do not store above 30°C.

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 Rowex contains

The active substance is dimethyl fumarate.

Dimethyl fumarate Rowex 120 mg hard gastro-resistant capsules: Each capsule contains 120 mg of dimethyl fumarate.

Dimethyl fumarate Rowex 240 mg hard gastro-resistant capsules: Each capsule contains 240 mg of dimethyl fumarate.

The other ingredients are capsule content: croscarmellose sodium (E468), silica, colloidal anhydrous (E551), sodium stearyl fumarate (E470A), methacrylic acid – methyl methacrylate copolymer (1:1), methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30%, talc (E553B), triethyl citrate (E1505), polysorbate 80 (E443), glycerol monostearate 40-55; capsule shell: gelatin (E441), titanium dioxide (E171), yellow iron oxide (E172), brilliant blue FCF (E133); capsule ink: shellac glaze~45% (20% esterified) (E904), black iron oxide (E172), propylene glycol (E1520), ammonium hydroxide 28%.

What Dimethyl fumarate Rowex looks like and contents of the pack

Gastro-resistant hard capsule (gastro-resistant capsule).

Dimethyl fumarate Rowex 120 mg hard gastro-resistant capsules

Hard capsules with white body and light-green cap with “120 mg” imprinted on the body. Size approx. 19 mm length and 9 mm width.

Dimethyl fumarate Rowex 240 mg hard gastro-resistant capsules

Hard light-green capsules with “240 mg” imprinted on the body. Size approx. 23 mm length and 9 mm width.

Dimethyl fumarate Rowex hard gastro-resistant capsules are packed in Al/PVC/PVDC blisters or calendar blisters or perforated unit dose blisters.

Dimethyl fumarate Rowex 120 mg hard gastro-resistant capsules

Pack sizes: blister with 14 or 28 gastro-resistant hard capsules.

Calendar blisters with 14 or 28 gastro-resistant hard capsules.

Perforated unit dose blisters of 14 x 1 gastro-resistant hard capsules.

Dimethyl fumarate Rowex 240 mg hard gastro-resistant capsules

Pack sizes: blisters with 28, 56, 168 or 196 gastro-resistant hard capsules.

Calendar blisters with 28, 56, 168 or 196 gastro-resistant hard capsules.

Perforated unit dose blisters 56 x 1 and 168 x 1 gastro-resistant hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

LEK Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

Zakłady Farmaceutyczne Polpharma S.A., Ul. Metalowca 2, 39-460 Nowa Dęba, Poland.

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

Austria	Dimethylfumarat 1A Pharma 120 mg – magensaftresistente Hartkapseln Dimethylfumarat 1A Pharma 240 mg – magensaftresistente Hartkapseln
Denmark	Dimethyl fumarate “1A Farma”, hårde enterokapsler
Finland	Dimethyl fumarate Sandoz 120 mg enterokapseli, kovat Dimethyl fumarate Sandoz 240 mg enterokapseli, kovat
Germany	Dimethylfumarat HEXAL 120 mg magensaftresistente Hartkapseln Dimethylfumarat HEXAL 240 mg magensaftresistente Hartkapseln
Hungary	Dimetil-fumarát Hexal 120 mg gyomornedvellenálló kemény kapszula Dimetil-fumarát Hexal 240 mg gyomornedvellenálló kemény kapszula
Iceland	Dimethyl fumarate 1A Farma 120 mg magasýrúþolið hart hylki Dimethyl fumarate 1A Farma 240 mg magasýrúþolið hart hylki
Ireland	Dimethyl fumarate Rowex 120 mg hard gastro-resistant capsules Dimethyl fumarate Rowex 240 mg hard gastro-resistant capsules
The Netherlands	Dimethylfumaraat Sandoz 120 mg, harde maagsapresistente capsules Dimethylfumaraat Sandoz 240 mg, harde maagsapresistente capsules
Norway	Dimethyl fumarate 1A Farma 120 mg enterokapsel, hard Dimethyl fumarate 1A Farma 240 mg enterokapsel, hard
Portugal	Fumarato de dimetilo Sandoz 120 mg cápsulas gastrorresistentes Fumarato de dimetilo Sandoz 240 mg cápsulas gastrorresistentes
Spain	Fumarato de dimetilo Sandoz Farmacéutica 120 mg cápsulas duras gastrorresistentes EFG Fumarato de dimetilo Sandoz Farmacéutica 240 mg cápsulas duras gastrorresistentes EFG
Sweden	Dimethyl fumarate 1A Farma 120 mg enterokapslar, hårda Dimethyl fumarate 1A Farma 240 mg enterokapslar, hårda

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