Package leaflet: Information for the patient

Vumerity 231 mg gastro-resistant hard capsules
diroximel 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 Vumerity is and what it is used for
2. What you need to know before you take Vumerity
3. How to take Vumerity
4. Possible side effects
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6. Contents of the pack and other information

1. What Vumerity is and what it is used for

What Vumerity is

Vumerity contains the active substance diroximel fumarate.

What Vumerity is used for

Vumerity is used to treat relapsing-remitting multiple sclerosis (MS) in adult patients.
MS is a long-term condition in which the immune system (the body's natural defences) malfunctions and attacks parts of the central nervous system (the brain, spinal cord and the optic nerve of the eye) causing inflammation that damages the nerves and the insulation around them. Relapsing-remitting MS is characterised by repeated attacks (relapses) on the nervous system. 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 Vumerity works

The medicine is thought to work by increasing the action of a protein called 'Nrf2' which regulates certain genes that produce 'antioxidants' involved in protecting cells from damage. This helps control the activity of the immune system and reduce damage to the brain and spinal cord.

2. What you need to know before you take Vumerity

Do not take Vumerity

- **if you are allergic to diroximel fumarate, related substances (called fumarates or fumaric acid esters)** 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

Vumerity may affect your **white blood cell counts**, your **kidneys** and **liver**. Before you start Vumerity, your doctor will do a blood test to count 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 white blood cells decrease during treatment, your doctor may consider additional tests or stop your treatment.

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 progressive multifocal leukoencephalopathy (PML). PML is a serious condition that may lead to severe disability or death. Read the information about 'PML and lower lymphocyte counts' in section 4 of this leaflet.

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

Flushing (reddening of the face and body) is a common side effect. Serious flushing with additional symptoms can be a sign of a severe allergic reaction and has been seen in a small number of patients – see 'Severe allergic reactions' in section 4 of this leaflet. Talk to your doctor if flushing is causing you problems, as your doctor may be able to give you medicine to treat this.

Vumerity can cause a serious allergic reaction known as a hypersensitivity reaction. You need to know about all of the important signs and symptoms to look out for while you are taking Vumerity. Read the information about 'Severe allergic reactions' in section 4 of this leaflet.

Shingles (*herpes zoster*) may occur with Vumerity treatment. In some cases, serious complications have occurred. **You should inform your doctor** immediately if you suspect you have any symptoms of shingles. These are listed in section 4 of this leaflet.

A rare but serious kidney disorder (Fanconi syndrome) has been reported for a medicine containing related active substances (dimethyl fumarate, in combination with other fumaric acid esters). If you notice you are passing more urine, are more thirsty and drinking more than normal, or if 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 and adolescents because there is limited experience to know how safe and effective Vumerity is in this population.

Other medicines and Vumerity

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)
- **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** (such as *aminoglycosides* 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 Vumerity 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.

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 Vumerity if you are pregnant unless you have discussed this with your doctor. This is because Vumerity could harm your unborn baby. If you are able to get pregnant, you should use reliable contraception.

Breast-feeding

It is not known whether diroximel fumarate or its metabolites pass into breast milk. Your doctor will help you decide whether you should stop breast-feeding or stop using Vumerity. This involves balancing the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines

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

3. How to take Vumerity

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

Starting dose

The recommended starting dose is 231 mg (one capsule) twice a day.
Take this starting dose for the first 7 days, then take the maintenance dose.

Maintenance dose

The recommended maintenance dose is 462 mg (two capsules) twice a day.

Vumerity is for oral use.

Swallow each capsule whole, with some water. Do not crush or chew or sprinkle the capsule contents on food as this may increase some side effects.

You can take Vumerity with a meal or on an empty stomach. If you have side effects such as flushing or stomach problems, taking it with food may reduce these symptoms.

If you take more Vumerity 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 Vumerity

Do not take a double dose to make up for a forgotten dose.

If there are still at least 4 hours until your next planned dose, you can take the missed dose. Otherwise skip the missed dose and take your next planned dose at the normal time.

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

PML and lower lymphocyte counts

The frequency of PML cannot be estimated from the available data (not known).

Vumerity 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 with the related medicine dimethyl fumarate 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 that suppresses 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 Vumerity treatment, it is very important that you speak to your doctor as soon as possible. Also speak with your partner or caregivers and tell them about your treatment. Symptoms might develop that you do not notice 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).

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 Vumerity 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

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

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*)
- digestive system problems *(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
- proteins (*albumin*) in urine (*proteinuria*)
- increase in levels of liver enzymes (*ALT, AST*) in the blood
- low levels of white blood cells (*lymphopenia, leukopenia*) 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

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 injury due to medicine and increase in levels of liver enzymes measured in blood tests (*ALT or AST in combination with bilirubin*)

Not known (frequency cannot be estimated from the available data)
- shingles (*herpes zoster*) 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*)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Vumerity

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 bottle and the carton after "EXP". The expiry date refers to the last day of that month.

Store below 25ºC.
Store in the original bottle in order to protect from moisture.

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 Vumerity contains

The active substance is diroximel fumarate.

Each capsule contains 231 mg of diroximel fumarate.

The other ingredients are: capsule contents: methacrylic acid-ethyl acrylate copolymer (1:1) type A; crospovidone type A; cellulose, microcrystalline; silica, colloidal anhydrous; triethyl citrate; talc; magnesium stearate; capsule shell: hypromellose; titanium dioxide (E171); potassium chloride; carrageenan; capsule print: black iron oxide (E172), shellac, potassium hydroxide.

What Vumerity looks like and contents of the pack

Vumerity 231 mg gastro-resistant hard capsules are white and printed with 'DRF 231 mg' in black ink.
Vumerity is available in packs containing 120 or 360 (3x120) capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in May 2026.