

## Consumer Medicine Information

This leaflet provides important information about using VUMERITY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VUMERITY.**

*Where to find information in this leaflet:*

1. Why am I using VUMERITY?
2. What should I know before I use VUMERITY?
3. What if I am taking other medicines?
4. How do I use VUMERITY?
5. What should I know while using VUMERITY?
6. Are there any side effects?
7. Product details

### 1. Why am I using VUMERITY?

**VUMERITY contains the active ingredient diroximel fumarate.**

**VUMERITY is used to treat relapsing multiple sclerosis (MS).**

**VUMERITY slows down the progression of physical disability in people with relapsing forms of MS and decreases the number of flare ups (relapses).**

**Some people feel better when they start to take VUMERITY. However, VUMERITY cannot repair damage that has already been caused by MS. When you start VUMERITY you might not notice an improvement, but VUMERITY may still be working to help prevent your MS from becoming worse.**

**The cause of MS is not yet known, MS affects the brain and spinal cord. In MS, the body's immune system reacts against its own myelin (the 'insulation' surrounding nerve fibres). In relapsing forms of MS, people have 'exacerbations' from time to time (e.g. blurred vision, weakness in the legs or arms, or loss of control of bowel or bladder function). They are followed by periods of recovery. Recovery may be complete or incomplete. If it is incomplete there is 'progression of disability'.**

**Diroximel fumarate decreases the inflammation in your brain that is caused by MS and thereby reduces nerve damage. VUMERITY works by reducing inflammatory responses in cells and helps to protect the central nervous system cells against attack. Inflammation of the brain is an important part of the MS disease process.**

**Safety and efficacy in children and adolescents aged less than 18 years have not been established.**

### 2. What should I know before I use VUMERITY?

#### Warnings

**Do not use VUMERITY if:**

- you are allergic to diroximel fumarate, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicine containing dimethyl fumarate.

- you are suspected to suffer from a rare brain infection called progressive multifocal leukoencephalopathy (PML) or if PML has been confirmed.
- you are being treated with other medicines containing fumaric acid or dimethyl fumarate (creams, tablets or capsules).
- always check the ingredients to make sure you can use this medicine.
- the medicine has expired according to the expiry date printed on the pack or if the pack is damaged or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

#### Check with your doctor if you:

- have any other medical conditions: liver problems, kidney problems, infections, stomach or bowel problems.
- recently received a vaccination.
- suspect you may have shingles.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

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. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

If you are able to get pregnant, you should use reliable contraception. Check with your doctor if you intend to become pregnant. There is no information on the use of VUMERITY during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether VUMERITY passes into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breast-feeding.