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Package leaflet: Information for the patient

polpharma

Dimethyl fumarate Polpharma 120 mg gastro-resistant capsules, hard
Dimethyl fumarate Polpharma 240 mg gastro-resistant capsules, hard

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 Polpharma is and what it is used for

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

What Dimethyl fumarate Polpharma is used for

Dimethyl fumarate Polpharma 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 Polpharma works
Dimethyl fumarate Polpharma 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 Polpharma

Do not take Dimethyl fumarate Polpharma:
- **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 Polpharma may affect your **white blood cell counts**, your **kidneys** and **liver**. Before you start Dimethyl fumarate Polpharma, 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 analytic measures or discontinue your treatment.

Talk to your doctor before taking Dimethyl fumarate Polpharma 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 progressive multifocal leukoencephalopathy (PML). PML is a serious condition that may lead to severe disability or death.

A rare but serious kidney disorder (Fanconi Syndrome) has been reported for 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 more thirsty 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
The warnings and precautions listed above also apply to children. Dimethyl fumarate Polpharma can be used in children and adolescents aged 13 years and above. No data are available in children below 10 years of age.

Other medicines and Dimethyl fumarate Polpharma
Tell your doctor or pharmacist if you are taking, have recently taken or might take any medicines, in particular:
- medicines that contain **fumaric acid esters** (fumarates) used to treat psoriasis
- **medicines that affect the body's immune system** including **other medicines used to treat MS**, such as fingolimod, natalizumab, teriflunomide, alemtuzumab, ocrelizumab or cladribine, or some commonly used **cancer** treatments (rituximab or mitoxantrone)
- **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 Polpharma 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 Polpharma with alcohol
Consumption of more than a small quantity (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 Polpharma, 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
Do not use Dimethyl fumarate Polpharma if you are pregnant unless you have discussed this with your doctor.

Breast-feeding
It is not known whether the active substance of Dimethyl fumarate Polpharma passes into breast milk. Dimethyl fumarate Polpharma should not be used during breast-feeding. Your doctor will help you decide whether you should stop breast-feeding, or stop using Dimethyl fumarate Polpharma. This involves balancing the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines
The effect of Dimethyl fumarate Polpharma on the ability to drive or use machines is not known. Dimethyl fumarate Polpharma is not expected to affect your ability to drive and use machines.

Dimethyl fumarate Polpharma contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per capsule, that is to say essentially "sodium-free".

3. How to take Dimethyl fumarate Polpharma

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

If you take more Dimethyl fumarate Polpharma 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 Polpharma
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 effects
Dimethyl fumarate Polpharma 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 Polpharma and call a doctor straight away

Very common side effects
These 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 Polpharma.

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 side effects
These 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 side effects
These may affect *up to 1 in 100 people:*
- allergic reactions (*hypersensitivity*)
- reduction in blood platelets

Not known (frequency cannot be estimated from the available data)
- liver inflammation and increase in levels of liver enzymes (*ALT or AST in combination with bilirubin*)
- 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 Yellow Card Scheme at: 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 Dimethyl fumarate Polpharma

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

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 Polpharma contains
- The active substance is dimethyl fumarate.

Dimethyl fumarate Polpharma 120 mg: Each capsule contains 120 mg of dimethyl fumarate.
Dimethyl fumarate Polpharma 240 mg: Each capsule contains 240 mg of dimethyl fumarate.
- The other ingredients are:

capsule content: croscarmellose sodium, silica, colloidal anhydrous, sodium stearyl fumarate, methacrylic acid - methyl methacrylate copolymer (1:1), methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent, talc, triethyl citrate, polysorbate 80, glycerol monostearate 40-55;
capsule: gelatin, titanium dioxide (E171), yellow iron oxide (E172), brilliant blue FCF (E133); capsule ink: shellac glaze, black iron oxide (E172), propylene glycol (E1520), ammonium hydroxide 28%.

What Dimethyl fumarate Polpharma looks like and contents of the pack
Dimethyl fumarate Polpharma 120 mg: hard gelatin capsules, length: 19 mm, with white body and light-green cap, with overprint on the body 120 mg and are available in packs containing 14 or 56 capsules.

Dimethyl fumarate Polpharma 240 mg: hard gelatin capsules, length: 23 mm, light-green, with overprint on the body 240 mg and are available in packs containing 56 or 168 capsules.

Not all pack sizes may be marketed.

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