Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only.

Dimethyl Fumarate Medomie 120 mg

Dimethyl Fumarate Medomie 240 mg

Delayed release capsules

Active ingredient and its quantity:

Each capsule contains: 120 mg or 240 mg dimethyl fumarate

Inactive ingredients and allergens: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not indicated for use in children below the age of 18. There is no information about the safety and efficacy of Dimethyl Fumarate Medomie in this age group.

1. What is this medicine intended for?

Dimethyl Fumarate Medomie is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis.

Therapeutic group: A medicine that affects the nervous system.

Multiple sclerosis is a chronic disease that affects the central nervous system, including the brain and the spinal cord. Relapsing-remitting multiple sclerosis 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 Medomie works

Dimethyl Fumarate Medomie seems to work by preventing the immune system from damaging your brain and spinal cord. This may also prevent future deterioration of your disease.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine.
- It is suspected or you have been tested and found to have a rare brain infection called progressive multifocal leukoencephalopathy (PML).

Special warnings about using this medicine

The medicine may affect your white blood cell counts, your kidneys and liver. Before you start treatment with Dimethyl Fumarate Medomie, 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 from time to time during treatment. If your number of white blood cells decreases during treatment, your doctor may consider adding additional analytical tests or interrupting your treatment.

- Inform your doctor if:
  - **you have a severe kidney disease**
  - **you have a severe liver disease**
  - **you have a digestive tract disease**
  - **you have a serious infection (such as pneumonia)**

Shingles may occur with Dimethyl Fumarate Medomie treatment. In some cases, serious complications will occur You should inform your doctor immediately if you suspect you have any symptoms of shingles.

If you believe that your multiple sclerosis is worsening (for example, weakness or changes in vision) or if you notice new symptoms, speak to your doctor immediately, as these may be symptoms of a rare brain infection called progressive multifocal leukoencephalopathy (PML). PML is a serious condition that can lead to severe disability or death.

Children and adolescents
Do not use Dimethyl Fumarate Medomie in children and adolescents under the age of 18 years. The efficacy and safety of the medicine in this age group is unknown.

Tests and follow-up
Before beginning and during use of the medicine, your doctor will refer you for blood tests, and kidney and liver function tests.

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. In particular, inform your doctor or pharmacist if you are taking:

- medicines that contain fumarates (derivatives of fumaric acid) for treatment of psoriasis
- medicines that affect the body's immune system, including additional medicines used to treat multiple sclerosis, such as fingolimod, natalizumab, teriflunomide, alemtuzumab, ocrelizumab, cladribine, or some commonly used cancer treatments (rituximab or mitoxantrone).
- vaccines - taking Dimethyl Fumarate Medomie 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.
- medicines that affect the kidneys, such as certain antibiotics (used to treat infections), (diuretics), certain types of painkillers (such as ibuprofen and other similar anti-inflammatories and non-prescription medications) and medicines that contain lithium.

Using this medicine and food
Take the medicine with food. It may help reduce some of the very common side effects (see section 4 'Side effects').

Using this medicine and alcohol consumption
Avoid consumption of a large quantity (more than a shot) of a strong alcoholic drink (more than 30% alcohol by volume) within a short period of taking Dimethyl Fumarate Medomie. Wait an hour between taking the medicine and the drink, as drinking alcohol within a short period of taking the medicine may increase side effects in the stomach, such as gastritis, especially in people prone to it.

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant or are planning to become pregnant, report this to your doctor as soon as possible. You and your doctor will discuss together whether you should continue this treatment.

Pregnancy
Do not take Dimethyl Fumarate Medomie if you are pregnant unless you have discussed this with your doctor.

Breastfeeding
It is not known whether the active ingredient of Dimethyl Fumarate Medomie passes into breast milk. Do not use this medicine during breastfeeding. Your doctor will help you decide whether you should stop breastfeeding or stop taking Dimethyl Fumarate Medomie after considering the possible benefit of breastfeeding your baby and the possible benefit of the therapy for you.

Driving and using machines
The effect of Dimethyl Fumarate Medomie on the ability to drive or use machines is not known. Use of Dimethyl Fumarate Medomie is not expected to affect your ability to drive and use machines. Ask your doctor if your disease allows you to perform these operations.

3. How to use this medicine?
Always use the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose and about how to take this medicine.

- Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually: The starting dose is 120 mg twice a day for 7 days, and then the regular dose is 240 mg twice a day. **Do not exceed the recommended dose**
- Swallow the medicine whole with water
- Do not divide, crush, dissolve, suck or chew the capsule, as this may increase some side effects.
- Taking Dimethyl Fumarate Medomie with food may help reduce some of the very common side effects (see section 4)

If you have accidentally taken a higher dose, contact a doctor.
If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the required time and if there are at least four hours until the time for the next dose, you may take the missed dose. Otherwise, take the next dose at the usual time. **Do not take a double dose**.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Dimethyl Fumarate Medomie may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

<u>Serious side effects:</u>

- Dimethyl Fumarate Medomie may cause a low lymphocyte (type of white blood cell) count. A low white blood cell count may increase your risk of infection, including a risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML).
  Progressive multifocal leukoencephalopathy (PML) may lead to severe disability or death. It was found that progressive multifocal leukoencephalopathy occurred after one to five years of treatment, and therefore, your doctor needs to continue to monitor your white blood count during treatment, and you should continue to pay attention to any possible symptom of PML, as explained below. The risk of progressive multifocal leukoencephalopathy may be higher if you have previously taken an immunosuppressive medicine.

- The symptoms of progressive multifocal leukoencephalopathy may be similar to a multiple sclerosis attack. The symptoms may include new or worsening weakness on one side of the body, clumsiness, changes in vision, thinking or memory, or confusion, personality changes, difficulty speaking and communicating that last for more than several days.
  If you think that your multiple sclerosis is worsening or if you notice new symptoms while you are taking Dimethyl Fumarate Medomie, it is very important that you speak to your doctor as soon as possible. Additionally, speak to your partner or medical team and let them know about your treatment. Symptoms may appear without your being aware of them yourself.
  Contact your doctor <u>immediately</u> if you suffer from one or more of the following symptoms.

- **Severe allergic reactions -**

The frequency of severe allergic reactions cannot be estimated from the available information (not known).

Flushing of the face or body is a very common side effect. However, if you have flushing that is accompanied by a red rash, hives **and one** of the following 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*)

These may represent a severe allergic reaction (*anaphylaxis*); **stop the treatment and call a doctor straight away**.

<u>Additional side effects:</u>

Very common side effects (effects that appear in more than 1 in 10 users)

Reddening of the face or body feeling warm, hot, burning or itchy, diarrhoea, feeling sick, Stomach pain or stomach cramps. Taking Dimethyl Fumarate Medomie with food can help reduce these side effects.

Ketones may appear in urine tests.

Consult with your doctor about how to treat these side effects. Your doctor may reduce your dose. Do not reduce your dose without explicit instruction from your doctor.

Common side effects (effects that appear in 1-10 in 100 users)

Inflammation of the lining of the intestines (gastroenteritis), burning sensation, hot flushes, vomiting, indigestion (dyspepsia), inflammation of the lining of the stomach (gastritis), gastrointestinal disorders, rash, redness of the skin (pink or red blotches - erythema), itchy skin, feeling hot.

Side effects that appear in blood or urine tests:

- Lower white blood cell count (lymphopenia, leukopenia) in the blood. Reduced white blood cells may indicate that your body is less able to fight infections. If you have a serious infection (such as pneumonia), contact your doctor immediately.
- Protein (albumin) in urine
- Increase in levels of liver enzymes (ALT, AST) in the blood.

Uncommon side effects - that appear in 1-10 in 1,000 users

- Allergic reaction (hypersensitivity)
- Reduction in blood platelets

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- Liver inflammation and increase in levels of liver enzymes (ALT or AST in combination with bilirubin).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:
Store below 25˚C. Protect from light.
After opening, can be kept for up to 30 days.

6. Additional information

- **In addition to the active ingredient, this medicine also contains**

Microcrystalline cellulose, methacrylic acid ethyl copolymer (1:1) dispersion 30%, croscarmellose sodium, talc, methacyrlic acid methyl methacrylate copolymer (1:1), colloidal silicon dioxide, triethyl citrate and magnesium stearate.
The capsule shell contains gelatin and titanium dioxide and is imprinted with black ink.

- **What the medicine looks like and contents of the pack:**
  - ❖ Dimethyl Fumarate Medomie 120 mg - a white gelatin capsule with "120 mg" printed in black ink. A bottle containing 14 capsules.
  - ❖ Dimethyl Fumarate Medomie 240 mg – a white gelatin capsule with "240 mg" printed in black ink. A bottle containing 60 capsules.

Registration holder's name and address: Medomie Pharma Ltd., POB 816, Givatayim 5358305

Manufacturer's name and address: MSN Laboratories Private Limited, Telangana, 509228 India

This leaflet was revised in July 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Dimethyl Fumarate Medomie 120 mg: 170-06-36832-99
Dimethyl Fumarate Medomie 240 mg: 170-07-36833-99