

# Sclera® 120 mg and 240 mg Gastro-resistant

## Hard 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The product is known by the name above but will be referred to as Sclera throughout the rest of this leaflet.

### In this leaflet:

1. What Sclera is and what it is used for
2. What you need to know before you take Sclera
3. How to take Sclera
4. Possible side effects
5. How to store Sclera
6. Contents of the pack and other information

### 1. What Sclera is and what it is used for

#### What Sclera is

Sclera is a medicine that contains the active substance dimethyl fumarate.

#### What Sclera is used for

Sclera is used to treat relapsing-remitting multiple sclerosis (MS) in adult patients. 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 Sclera works

Sclera 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 Sclera

#### Do not take Sclera

- 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

Sclera may affect your white blood cell counts, your kidneys and liver. Before you start Sclera, 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 Sclera 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 Sclera 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

Sclera is not recommended for use in children and adolescents because there is limited experience in the use of dimethyl fumarate in this population.

#### Other medicines and Sclera

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, teriflumonomide, 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 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.

#### Sclera 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 Sclera, 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 Sclera if you are pregnant unless you have discussed this with your doctor.

#### Breast-feeding

It is not known whether the active substance dimethyl fumarate passes into breast milk. Sclera should not be used during breast-feeding. Your doctor will help you decide whether you should stop breast-feeding or stop using Sclera. 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 on the ability to drive or use machines is not known. Sclera is not expected to affect your ability to drive and use machines.

#### Sclera contains sodium and tartrazine - FD&C yellow

Sclera contains sodium. Each gastro-resistant hard capsule of Sclera 120 mg and 240 mg Gastro-resistant Hard Capsules contains 1.326 mg or 2.651 mg sodium, respectively. This medicine contains less than 1 mmol sodium (23 mg) per gastro-resistant hard capsule, that is to say essentially 'sodium-free'.

Sclera contains tartrazine - FD&C yellow. Each gastro-resistant hard capsule of Sclera 120 mg and 240 mg Gastro-resistant Hard Capsules contains 0.00438 mg or 0.016352 mg tartrazine - FD&C yellow, respectively. It may cause allergic reactions.

### 3. How to take Sclera

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.

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

#### If you take more Sclera 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 Sclera

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 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 (dyspnea, hypoxia).
- Dizziness or loss of consciousness (hypotension).

Then this may represent a severe allergic reaction (anaphylaxis).

Stop taking dimethyl fumarate 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.

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)

#### 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)

- Worsening of 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.

### 5. How to store Sclera

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

Do not store above 30°C.

Store in the original package in order to protect from light.

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

Do not use this medicine if you notice any visible signs of deterioration.

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 Sclera contains

The active ingredient is dimethyl fumarate.

Each gastro-resistant hard capsule of Sclera 120 mg Gastro-resistant Hard Capsules contains 120 mg

dimethyl fumarate.

Each gastro-resistant hard capsule of Sclera 240 mg Gastro-resistant Hard Capsules contains 240 mg

dimethyl fumarate.

The other ingredients are: **Capsule content:** Microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, methacrylic acid copolymer type A, methacrylic acid copolymer 30% dispersion, triethyl citrate and talc. **Capsule shell:** Gelatin, titanium dioxide, brilliant blue FCF-FD&C blue and tartrazine - FD&C yellow.

#### What Sclera looks like and contents of the pack

Sclera 120 mg Gastro-resistant Hard Capsules are size (1) green cap/white body hard gelatin capsules, imprinted with "H1 120" in clear PVC/Aclar-aluminum blisters.

Pack size: 14 Gastro-resistant Hard Capsules.

Sclera 240 mg Gastro-resistant Hard Capsules are size (0E) green cap/green body hard gelatin capsules, imprinted with "H1 240" in clear PVC/Aclar-aluminum blisters.

Pack size: 56 Gastro-resistant Hard Capsules.

#### Marketing Authorization Holder and Manufacturer

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#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

• Jordan

Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance Department

Tel: + (962-6) 5832000

E-mail: jpc@fdaj.jo

Website: www.fda.jo

Smart phones application: JFDA

Paper reporting form: Yellow card

### Council of Arab Health Ministers, Union of Arab Pharmacists

#### This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.



Size:  
170x250 mm

Pantone.  
2766