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## PACKAGE LEAFLET: INFORMATION FOR THE USER

### ISMO Retard 40 mg prolonged-release tablets



isosorbide-5-mononitrate

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

#### 1. What ISMO Retard is and what it is used for

ISMO Retard belongs to a group of medicines called nitrates. The nitrates make the arteries of the heart dilate, increasing the blood supply to the heart muscle.

ISMO Retard is used to treat angina pectoris. Angina pectoris is a type of chest pain caused when your heart muscle does not get enough blood supply. ISMO Retard will help to:

- lower the number of episodes of angina
- lower the severity of your attacks of your angina

#### 2. What you need to know before you take ISMO Retard

##### Do NOT take ISMO Retard

- if you are allergic to isosorbide-5-mononitrate or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to isosorbide dinitrate (the same type of medicine as ISMO Retard)
- if you have marked low blood pressure (systolic blood pressure  $\leq 90$  mmHg)
- if you suffer from circulatory collapse or shock
- if you suffer from cardiogenic shock
- if you suffer from acute myocardial infarction with low left ventricular filling pressure
- if you have been diagnosed with any of the following:
  - hypertrophic obstructive cardiomyopathy (a thickened heart muscle),
  - constrictive pericarditis (an inflammation of the heart sac),
  - cardiac tamponade (accumulation of fluid around the heart),
  - aortic/mitral valve stenosis (narrowing of heart valves)
- if you suffer from severe anaemia (low level of red blood cells)
- if you suffer from closed angle glaucoma (high pressure in the eye)
- if you suffer from conditions associated with raised pressure on the brain (e.g. following head trauma and cerebral haemorrhage)
- if you suffer from severe hypovolaemia (decreased blood volume)
- if you are taking sildenafil (as in Viagra®), vardenafil or tadalafil used in the treatment of male erectile dysfunction (when you cannot get an erection)

##### Warnings and precautions

Talk to your doctor or pharmacist before taking ISMO Retard.

ISMO Retard is used to stop angina attacks from happening. It is not intended to treat a sudden attack of angina.

Patients who have not previously received nitrates may initially be started with a low dose which should be gradually increased before introducing ISMO Retard. The lowest effective dose should be used.

Do not stop taking ISMO Retard suddenly. It should be withdrawn gradually.

##### Take special care with ISMO Retard, if

- you suffer from hypothyroidism (your thyroid gland does not produce sufficient amounts of thyroid hormone)
- you suffer from malnutrition
- you have severe problems with your liver or kidneys
- you have low body temperature (hypothermia)
- you have recent history of myocardial infarction (heart attack)
- if you are already taking medicine to lower blood pressure
- you are taking any other medication
- you are pregnant or breast-feeding

**If any of the above apply to you, you should not take this medicine until you have talked to your doctor about it.**

A low blood pressure caused by nitrates may occur with paradoxical bradycardia (slowing of the heart rate) and worsening of the symptoms of angina.

A severe drop in blood pressure, when standing up or move suddenly, with light-headedness and dizziness is frequently observed after drinking alcohol.

You can develop a tolerance to this medicine or if you are taking another medicine containing nitrates. In order to avoid any lessening or loss of the effect of the medicine, you should not take high doses on a continual basis.

Taking ISMO Retard may cause transient hypoxaemia (an abnormally low level of oxygen in the blood). This happens because blood flow in your body is redistributed with an increase in perfusion of poorly ventilated areas of the lung. This may cause ischaemia (not enough blood going to your heart muscle) if you have coronary heart disease.

Increasing doses and/or changes in intervals between doses can lead to this medicine not working with the effect that it should or not work at all.

#### Children

The safety and effectiveness of ISMO Retard in children has not been established.

#### Other medicines and ISMO Retard

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking the following medicines at the same time as ISMO Retard can increase the blood pressure lowering (hypotensive) effect of ISMO Retard:

- other vasodilators,
- antihypertensives (medicines to treat high blood pressure) such as ACE-inhibitors, angiotensin-II-receptor antagonists, beta-blockers, calcium antagonists and diuretics,
- neuroleptics (used to treat psychiatric disorders),
- sapropterin (used to lower phenylalanine levels in the blood of patients with phenylketonuria),
- alprostadil (for male erection problems),
- aldesleukin (for cancer treatment), and
- alcohol

#### You must not take any treatments for erectile dysfunction whilst taking ISMO Retard.

Do not take sildenafil (as in Viagra®), vardenafil or tadalafil whilst taking ISMO Retard. Treatments for erectile dysfunction can cause a severe and dangerous fall in blood pressure when taken together with ISMO Retard. This can be fatal.

#### ISMO Retard with food, drink and alcohol

Do not drink alcohol whilst taking ISMO Retard as it may increase the blood pressure lowering (hypotensive) effect of ISMO Retard.

#### Pregnancy, breast-feeding and fertility

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

There is insufficient experience with the use of isosorbide-5-mononitrate in pregnant women. Animal studies having shown no adverse effects on the foetus. Use of ISMO Retard in pregnancy is not recommended unless considered essential by your doctor.

#### Lactation

It is unknown, if isosorbide-5-mononitrate is excreted in breast milk. Use during breast-feeding is not recommended unless considered essential by your doctor.

#### Fertility

There are no fertility data.

#### Driving and using machines

When you take ISMO Retard you may feel dizzy or light-headed if you stand up or move suddenly. You may experience blurred vision.

If you experience such symptoms you should not drive or operate machinery.

#### ISMO Retard contains glucose, sucrose and milk sugar (lactose)

ISMO Retard contains less than 36 mg milk sugar (lactose) per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3. How to take ISMO Retard

Always take ISMO Retard exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet per day. Your doctor will tell you how many to take.

You should always take ISMO Retard in the morning. You should swallow the tablets whole, with a drink of water.

#### Duration of treatment

Angina needs long-term treatment.

Keep taking your ISMO Retard unless your doctor tells you to stop.

#### If you take more ISMO Retard than you should

If you have taken too many tablets (overdose), tell your doctor at once, or contact the nearest hospital casualty department. If you feel faint or dizzy, lie flat with your legs raised higher than your head.

Symptoms of an overdose may be the following: nausea, vomiting, restlessness, warm flushed skin, blurred vision, headache, fainting, tachycardia (a fast heart beat), hypotension and palpitations.

At high doses (more than 20 mg/kg body weight), methaemoglobin formation (an oxidation form of haemoglobin in the blood), bluish discoloration of the skin and mucous membranes due to reduced oxygen content of the blood (cyanosis), shortness of breath (dyspnoea) and rapid shallow breathing (tachypnoea) can be expected.

At very high doses, increased pressure within the skull (intracranial pressure) with related symptoms may occur.

#### If you forget to take ISMO Retard

If you forget to take a tablet, take one as soon as you remember on that day. Continue your treatment as usual the following morning.

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

#### If you stop taking ISMO Retard

You may feel unwell if you suddenly stop taking ISMO Retard. Tell your doctor if you stop taking this medicine.

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.

If you develop chest pains or experience worsening of chest pains, contact your doctor.

If you experience any of the following side effects, please tell your doctor or pharmacist.

#### Very Common (in more than 1 in 10 patients treated)

- Particularly at the start of treatment, a temporary “nitrate headache” may occur which normally subsides after some days of continued treatment.

#### Common (in 1 to 10 out of 100 patients treated)

- low blood pressure (hypotension) and/or drop in blood pressure when standing up or move suddenly (postural hypotension), especially at the beginning of treatment, which may be accompanied by a fast heart beat (tachycardia), slight states of dizziness or feeling weak
- gastro-intestinal symptoms, e.g. nausea and/or vomiting, especially when first used

#### Uncommon (in 1 to 10 out of 1,000 patients treated)

- significant drop in blood pressure may lead to an increase in chest pain (exacerbation of angina pectoris symptoms)
- states of collapse, sometimes with bradyarrhythmias (slowing of the heart beat) and syncope (fainting)
- skin flushing
- allergic skin reactions

#### Not known (frequency cannot be estimated from the available data)

- heartburn
- formation of methaemoglobin, in particular in susceptible patients such as those with methaemoglobin reductase deficiency or in patients with diaphorase deficiency and abnormal haemoglobin structure
- severe hypotensive responses including nausea, vomiting, restlessness, pallor, and excessive sweating have been reported for organic nitrates
- severe inflammatory skin disease (exfoliative dermatitis)

#### 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](http://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 ISMO Retard

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

Do not use this medicine after the expiry date which is stated on the blister strip and carton. 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 of medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

#### What ISMO Retard contains

The active substance is:

- isosorbide-5-mononitrate

Each ISMO Retard prolonged-release tablet contains 40 mg of isosorbide-5-mononitrate.

#### The other ingredients are

Tablet:

- anhydrous lactose
- montan glycol wax
- povidone K25
- colloidal silicon dioxide
- magnesium stearate

Sugar coating:

- methacrylic acid copolymer
- talc
- sucrose
- kaolin
- macrogol 35000
- titanium dioxide
- povidone K25
- liquid glucose
- montan glycol wax.

#### What ISMO Retard 40 mg tablets look like and contents of the pack

ISMO Retard 40 mg tablets are round and white. ISMO Retard 40 mg tablets are available in blister strips.

Pack sizes:

Packs of 28 or 30 tablets.

#### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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**This leaflet was last revised in 12/2021.**