

PACKAGE LEAFLET:
INFORMATION FOR THE USER

ISMO® 10

10 mg 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® 10 is and what it is used for
2. What you need to know before you take ISMO® 10
3. How to take ISMO® 10
4. Possible side effects
5. How to store ISMO® 10
6. Contents of the pack and other information

1. WHAT ISMO® 10 IS AND WHAT IT IS USED FOR

ISMO® 10 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® 10 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® 10 will help to:
 - lower the number of your episodes of angina
 - lower the severity of your attacks of angina
- heart failure (when your heart cannot pump enough blood around the body)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISMO® 10

Do NOT take ISMO® 10

- 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® 10)
- 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® 10.

ISMO® 10 is used to stop angina attacks from happening. It is not intended to treat a sudden attack of angina.

The lowest effective dose should be used.

Do not stop taking ISMO® 10 suddenly. It should be withdrawn gradually.

Take special care with ISMO® 10, 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)
- 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® 10 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® 10 in children has not been established.

Other medicines and ISMO® 10

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® 10 can increase the blood pressure lowering (hypotensive) effect of ISMO® 10:

- 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® 10.

Do not take sildenafil (as in Viagra®), vardenafil or tadalafil whilst taking ISMO® 10. Treatments for erectile dysfunction can cause a severe and dangerous fall in blood pressure when taken together with ISMO® 10. This can be fatal.

ISMO® 10 with food, drink and alcohol

Do not drink alcohol whilst taking ISMO® 10 as it may increase the blood pressure lowering (hypotensive) effect of ISMO® 10.

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® 10 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.

Description:	Ismo 10 mg Mock up
Country/Lang.:	Großbritannien
Date/Time:	28.01.2022 07:48 Artensis
Material No.:	XXXXXXXXXX
MAH No.:	
Manufact. No.:	XXXXXXXX-XX
Dimensions/TD:	155x390mm Esp. P019
Color:	P 281
Cutting die:	Cyan
LAETUS Code:	182
Font Type/Size:	CentSchbook BT 8 Pkt.
SKU/DU:	4000171

Fertility

There are no fertility data.

Driving and using machines

When you take ISMO® 10 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® 10 contains milk sugar (lactose)

ISMO® 10 contains 74 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® 10

Always take ISMO® 10 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 4 to 6 tablets per day (40 mg – 60 mg), but can range from 20 mg to 120 mg daily. Your doctor will tell you how many to take.

You should always take ISMO® 10 at the times your doctor has told you to take it. You should swallow the tablets whole, with a drink of water.

If you have not taken ISMO® 10 before, your doctor may tell you to take less ISMO® 10 for a few days, i.e. 10 mg daily (one tablet) for 2 days, followed by 20 mg daily (one tablet in the morning and one in the evening) for a further 3 days.

Duration of treatment

Angina needs long-term treatment.

Keep taking ISMO® 10 unless your doctor tells you to stop.

If you take more ISMO® 10 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® 10

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® 10

You may feel unwell if you suddenly stop taking ISMO® 10. 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 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® 10

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 medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ISMO® 10 tablets contain

The active substance is:

- isosorbide-5-mononitrate

Each ISMO® 10 tablet contains 10 mg isosorbide-5-mononitrate.

The other ingredients are:

- anhydrous lactose
- colloidal silicon dioxide
- magnesium stearate

What ISMO® 10 tablets look like and contents of the pack

ISMO® 10 tablets are round and white. Each tablet is marked “ISMO®” on one face and “10” on the reverse.

ISMO® 10 tablets are available in blister strips.

Pack sizes:

Packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Esteve Pharmaceuticals GmbH
Hohenzollerndamm 150-151
14199 Berlin
Germany
phone +49 30 338427-0
e-mail info.germany@esteve.com

Manufacturer

Kern Pharma S.L.
Polígono Ind. Colón II
Venus, 72
08228 Terrassa (Barcelona)
Spain

This leaflet was last revised in 12/2021.

xxxxxxx

xxxxxx-xx