

PATIENT INFORMATION LEAFLET

MONICOR 60 mg SR

SCHEDULING STATUS

S3

MONICOR 60 mg SR slow release film coated tablets

Isosorbide-5-mononitrate

MONICOR 60 mg SR contains sugar (lactose 38,17 mg per tablet)

Read all of this leaflet carefully before you start taking MONICOR 60 mg SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MONICOR 60 mg SR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MONICOR 60 mg SR is and what it is used for
2. What you need to know before you take MONICOR 60 mg SR
3. How to take MONICOR 60 mg SR
4. Possible side effects
5. How to store MONICOR 60 mg SR
6. Contents of the pack and other information

1. What MONICOR 60 mg SR is and what it is used for

MONICOR 60 mg SR contains an active substance called isosorbide-5- mononitrate. This belongs to a group of medicines called 'nitrates'. It works by improving the supply of blood and oxygen to the heart muscle. The tablets will release your medicine slowly and will treat your condition throughout the day. MONICOR 60 mg SR is prescribed by doctors for the preventative treatment of angina pectoris, a condition characterised by frequent and intense pain in the chest.

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2. What you need to know before you take MONICOR 60 mg SR

Do not take MONICOR 60 mg SR:

- if you are hypersensitive (allergic) to isosorbide-5-mononitrate, organic nitrate type medications or any of the other ingredients of MONICOR 60 mg SR (listed in section 6)
- if you have very low blood pressure, a low amount of blood in the body, a clear reduction in the amount of red blood cells in the body (severe anaemia), a weak heart due to blockage of your heart arteries or increased pressure in the skull due to head injury or bleeding in the brain
- if you have a heart problem called cardiomyopathy (chronic disease of the heart muscle) or pericarditis (swelling and irritation of the thin, sac-like membrane surrounding the heart) or you have narrow heart valves
- if you have angle closure glaucoma (increased pressure in the eye/eyes), as MONICOR 60 mg SR may increase the pressure in the eye further
- if you are also taking sildenafil, a medicine used to treat a man who cannot get or keep a hard, erect penis suitable for sexual activity, or other similarly acting medicines (see Other medicines and MONICOR 60 mg SR)
- for the relief of sudden attacks of angina pectoris. Your doctor will prescribe sublingual (under the tongue) nitroglycerin tablets to be used in these situations (see How to take/use MONICOR 60 mg SR).

Warnings and precautions

Take special care with MONICOR 60 mg SR:

- if you have severe cerebral arteriosclerosis (hardening and/or thickening of the walls of the smaller arteries of the brain) or severe low blood pressure (see Do not take MONICOR 60 mg SR)
- if you are undernourished, have severely weakened kidney or liver function, decreased function of the thyroid gland, malnutrition, or have a low body temperature
- if you have angle closure glaucoma (increased pressure in the eye/eyes), as MONICOR 60 mg

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SR may increase the pressure in the eye further (see Do not take MONICOR 60 mg SR).

Other medicines and MONICOR 60 mg SR

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- if you intend taking alcohol or other medicines that cause widening of the blood vessels, these may cause excessive lowering of blood pressure
- sildenafil and other medicines used to treat a man who cannot get or keep a hard, erect penis suitable for sexual activity
- other antihypertensive medicines (medicines used for high blood pressure).

MONICOR 60 mg SR with food and drink

MONICOR 60 mg SR can be taken with or without food.

MONICOR 60 mg SR tablets can be broken into two, but should not be chewed or crushed and should be taken with half a glass of water.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MONICOR 60 mg SR.

DO NOT take MONICOR 60 mg SR if you are pregnant, suspect that you are pregnant or are breastfeeding, as the safety of MONICOR 60 mg SR in pregnancy and breastfeeding is not known.

Driving and using machines

MONICOR 60 mg SR may impair your ability to drive and use machinery. Take care if you feel dizzy, tired, or drowsy while using MONICOR 60 mg SR, especially if other blood-pressure lowering

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medications are taken at the same time.

It is not always possible to predict to what extent MONICOR 60 mg SR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MONICOR 60 mg SR affects them.

MONICOR 60 mg SR contains lactose

MONICOR 60 mg SR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MONICOR 60 mg SR.

3. How to take MONICOR 60 mg SR

Do not share medicines prescribed for you with any other person. Always take MONICOR 60 mg SR exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is one MONICOR 60 mg SR tablet daily, in the morning. This dosage may be increased to two MONICOR 60 mg SR tablets once daily, in the morning.

Treatment may be started with a half MONICOR 60 mg SR tablet daily, in the morning for the first two to four days to decrease the possibility of headache.

MONICOR 60 mg SR tablets may be broken in half, but should not be chewed or crushed and should be taken with half a glass of water.

Elderly patients:

If you are an elderly person, your dosage should be the same as above, unless you suffer from low blood pressure or have a severe liver or kidney disorder – in which case you should follow your doctor's instructions. If you are already taking medication such as beta blockers (to reduce the speed and force of your heartbeat) or calcium channel blockers (to lower blood pressure), let your doctor know, as he/she may need to adjust your dose of MONICOR 60 mg SR or existing treatment.

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Children:

MONICOR 60 mg SR tablets are not for use in children.

Your doctor will tell you how long your treatment with MONICOR 60 mg SR will last. Do not stop treatment early because your condition may worsen.

If you have the impression that the effect of MONICOR 60 mg SR is too strong or too weak, tell your doctor or pharmacist.

MONICOR 60 mg SR may be used on its own or in combination with other medicines to control angina pectoris.

NOTE:

MONICOR 60 mg SR tablets are not to be used for the relief of sudden attacks of angina pectoris.

If you take more MONICOR 60 mg SR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- pulsing headache, excitation, flushing, cold perspiration, nausea, vomiting, vertigo, fainting, rapid heartbeat and low blood pressure.

If you forget to take MONICOR 60 mg SR

If you forget to take MONICOR 60 mg SR, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MONICOR 60 mg SR

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Do not suddenly stop taking MONICOR 60 mg SR, as this could make your angina worse.

If your treatment is to be stopped this should be done gradually. Be sure to follow your doctor's instructions.

4. Possible side effects

MONICOR 60 mg SR can have side effects.

Not all side effects reported for MONICOR 60 mg SR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using MONICOR 60 mg SR, please consult your healthcare provider for advice.

If any of the following happens, stop taking MONICOR 60 mg SR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MONICOR 60 mg SR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- rapid and irregular heartbeat, severe or prolonged headache, difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness, restlessness
- low blood pressure (tiredness, dizziness), headache

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- nausea
- flushing of the face.

Less frequent side effects:

- methaemoglobinaemia (a blood disorder in which too little oxygen is delivered to your cells)
- blurred vision
- vomiting, diarrhoea
- a bluish discolouration of the skin (cyanosis), rash, itching
- muscle aches and pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by either of the following links: <https://www.sahpra.org.za/Publications/Index/8> or <http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>.

By reporting side effects, you can help provide more information on the safety of MONICOR 60 mg SR.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store MONICOR 60 mg SR

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original container.

Protect from light.

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Keep the container tightly closed.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MONICOR 60 mg SR contains:

The active ingredient is isosorbide-5-mononitrate.

Each tablet contains 60 mg isosorbide-5-mononitrate.

The other ingredients are:

Tablet cores:

Carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, silica colloidal anhydrous, stearic acid.

Film coating:

Ferric oxide (Yellow iron oxide), hypromellose, macrogol, magnesium stearate, talc, titanium dioxide.

What MONICOR 60 mg SR looks like and contents of the pack

MONICOR 60 mg SR tablets are cream coloured, oval tablets, half-scored on both sides, marked with "60" on one side.

MONICOR 60 mg SR tablets are packed in a white plastic securitainer containing 30 tablets.

MONICOR 60 mg SR is also packed in hard silver-coloured aluminium foil and clear transparent PVC/PVDC film blister strips, available in a pack size of 30 tablets inside an outer carton.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

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MONICOR 60 mg SR

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