PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

ISOKET 0,1 % SOLUTION

Solution for infusion

Isosorbide dinitrate

Sugar-free

Read all of this leaflet carefully before you are administered ISOKET.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ISOKET 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 ISOKET is and what it is used for
2. What you need to know before you receive ISOKET
3. How to receive ISOKET
4. Possible side effects
5. How to store ISOKET
6. Contents of the pack and other information.

1. What ISOKET is and what it is used for:

ISOKET belongs to a group of medicines called organic nitrates. ISOKET is used to treat acute heart failure (heart problems that can cause shortness of breath or ankle swelling) and heart attack (myocardial infarction) and severe chest pain (angina pectoris).

2. What you need to know before you receive ISOKET:

You should not receive ISOKET if:

- you are hypersensitive (allergic) to isosorbide dinitrate, other nitrates or any of the other ingredients of ISOKET (listed in section 6)
- you have any serious heart problems e.g.
  - low filling pressures of the heart like during a heart attack or in left ventricular failure
  - conditions which affect the ability of your heart to function as a pump (cardiac tamponade or hypertrophic obstructive cardiomyopathy)
  - your heart is not delivering enough oxygen around your body (cardiogenic shock)
  - inflammation of the sack-like covering of the heart (constrictive pericarditis)
  - narrowing of the heart valves (aortic or mitral valve stenosis)
- you have very low blood pressure
- you suffer from anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- you have had a brain haemorrhage (bleeding)
- you have had a head injury (head trauma) or raised intracranial pressure (high pressure within your skull)
- you have a low blood volume (hypovolaemia)
- you have an eye disease called glaucoma
- your blood has stopped circulating around your body properly (circulatory failure or collapse)

- you are taking male sexual performance enhancing medicines (e.g. sildenafil, tadalafil, vardenafil) or similar medicines
- you are medicines that contain riociguat (used to treat pulmonary hypertension).

If any of the above applies to you talk to your doctor before you are administered ISOKET.

Warnings and precautions:

Check with your doctor before receiving ISOKET if:

- you have hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
- you are malnourished (severely underfed)
- you have severe liver or kidney disease
- you suffer from hypothermia (a very low body temperature)
- you suffer from orthostatic hypotension (where you may have a rapid heart rate and light-headedness on standing)
- You have an abnormally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischaemic heart disease.

Children and adolescents:

ISOKET is not suitable for children.

Other medicine and ISOKET:

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

DO NOT USE ISOKET if you are taking male sexual performance enhancing medicines (e.g. sildenafil) or similar medicines. Using ISOKET with these medicines could cause your blood pressure to fall to a dangerously low level.

DO NOT USE ISOKET with medicines containing riociguat.

Tell your doctor if you are taking any of the following medicines:

- Medicines to lower your blood pressure. They could increase the effect of ISOKET and lower your blood pressure too much.
- Monoamine oxidase inhibitors (used to treat depression).
- Tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat schizophrenia). These may also increase the effect of ISOKET.
- Ergotamine-containing medicine (used to treat migraine). This could increase your blood pressure too much.
- Sapropterin used for phenylketonuria (a birth defect that caused a build-up of the amino acid phenylalanine in the body).

If any of the above applies to you, talk to your doctor or nurse.

Receiving ISOKET with food and drink:

Do not drink alcohol. It could increase the effect of ISOKET and lower your blood pressure too much. If this happens, you may feel dizzy or faint.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before ISOKET is administered to you.

Driving and using machines:

ISOKET may give you a headache, or make you feel dizzy or tired. If this happens to you, do not drive or operate machinery. ISOKET may influence your reactivity which will have an effect on your ability to drive and operate machinery. This effect is worse if take alcohol.

ISOKET contains sodium chloride:

ISOKET 1mg/mL contains 3,54 mg/mL of sodium and may not be suitable for people on a low sodium diet. Tell your doctor before you are given ISOKET if this applies to you.

3. How to receive ISOKET:

You will never be expected to give yourself ISOKET. It will always be given to you by a person who is qualified to do so.

How much ISOKET is given:

Your doctor will choose the dose that is right for you. If you have any questions, ask your doctor.

How ISOKET is given:

ISOKET is a concentrate for intravenous infusion (injected into a vein).

ISOKET is a concentrate and must be diluted before use. Your doctor or nurse will dilute ISOKET with either saline (salt water) or glucose solution before it is given to you.

As ISOKET is used in hospital, your heartbeat (pulse) and blood pressure will be carefully monitored whilst you are being given ISOKET. This is to make sure that ISOKET is working properly and that the dose you are receiving is right for you.

If you have the impression that the effect of ISOKET is too strong or too weak, tell your doctor.

If you are given too much ISOKET:

As ISOKET will be given to you by a doctor or nurse, it is unlikely that you will be given too much or too little. However, in the event of overdosage your doctor will manage the overdosage.

An overdose of ISOKET may cause your blood pressure to be too low resulting in paleness, sweating, weak pulse, fast heartbeat, light-headedness on standing, headache, weakness, dizziness, feeling sick (nausea), being sick (vomiting) and diarrhoea.

If you forget to receive ISOKET:

Since a healthcare provider will administer ISOKET, it is unlikely that the dose will be missed.

4. Possible side effects:

ISOKET can have side effects.

Not all side effects reported for ISOKET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your health care provider for advice.

If any of the following happens, stop receiving ISOKET and tell our doctor immediately:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to ISOKET. 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:

- very low blood pressure which may cause the symptoms of angina (chest pain) to be increased
- allergic skin rash (sometimes these can be severe e.g. Steven-Johnson syndrome or exfoliative dermatitis)
- fainting and collapse.

- hypoxia (an absence of enough oxygen in the tissues to sustain bodily functions) with symptoms such as shortness of breath, confusion and restlessness.

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*:**

- headache, dizziness, light headedness when in the upright position and drowsiness
- have a faster heartbeat (tachycardia)
- feeling of weakness.

Less frequent side effects:

- flushing
- feeling sick (nausea), being sick (vomiting) and sometimes heartburn

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ISOKET.

5. How to store ISOKET:

Store at or below 30 °C, protected from light.

Discard any unused solution.

Store all medicines out of reach of children

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

6. Contents of the pack and other information:

What ISOKET contains:

The active substance is isosorbide dinitrate.

ISOKET 0,1 % SOLUTION is a concentrated solution of isosorbide dinitrate 1 mg/1 mL in sterile isotonic saline.

The inactive ingredients include sodium chloride, water for injections, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment).

What ISOKET looks like and contents of the pack:

A clear colourless solution in 10 mL ampoules.

ISOKET is filled into 10 mL colourless, OPC Type I glass ampoules.

Each pack contains 10 x 10 mL ampoules (10 mg/10 mL).

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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