PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ESMOCARD 100 mg/10 mL, Solution for infusion

esmolol hydrochloride (10 mg/ mL)

Sugar free

Read all of this leaflet carefully before you are given ESMOCARD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ESMOCARD 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 ESMOCARD is and what it is used for

ESMOCARD belongs to the group of beta-blockers. These substances slow down the heartbeat.

ESMOCARD is used for short term treatment in case of rapid heart rhythm disorders (tachycardia). It is also used during or after surgery in case of tachycardia and/or if the blood pressure gets too high (hypertension).

2. What you need to know before you use ESMOCARD

ESMOCARD should not be administered to you:

- if you are hypersensitive (allergic) to esmolol or any of the other ingredients of ESMOCARD (listed in section 6) or other beta-blockers (cross sensitivity between beta-blockers is possible)
- if your heartbeat is very slow (heart rate less than 50 beats per minute)
- if you have a fast or alternating fast and slow heartbeat
- if you suffer from a block in the conduction of electrical signals that control heart function (heart block greater than first degree)
- if you suffer from heart failure that are not currently controlled
- if you have a problem with the blood supply to your heart or suffer from shock due to defective heart function (cardiogenic shock)
- if you have low blood pressure
- if you are receiving or have recently received verapamil. You must not be given ESMOCARD within 48 hours of when you stop receiving verapamil
- if you have a condition called pheochromocytoma which has not yet been treated (it is a tumour of the adrenal gland which can lead to a sudden increase in blood pressure, severe headache, sweating and increased heartbeat)
- if you have increased blood pressure in the lungs (pulmonary hypertension)
- if you suffer from asthma symptoms that are worsening rapidly or have a history of chronic respiratory diseases such as bronchitis
- if you have increased levels of acids in your body (metabolic acidosis)
- if you have a blood circulation disorder of which causes paleness of the skin and pain in the fingers and toes (Raynaud's phenomenon).

The normal dose should be reduced in elderly patients, or in patients suffering from renal dysfunction.

Warnings and precautions

Tell your doctor or health care provider before being given the injection.

Special care should be taken with ESMOCARD:

- if you are being treated for certain heart rhythm disorders called supraventricular arrhythmias and you have other heart problems or are taking other heart medicines. Treatment with ESMOCARD in this way can lead to severe reactions which may be fatal including: loss of consciousness; shock (when your heart does not pump enough blood) and heart attack (cardiac arrest).
- if you have low blood pressure (hypotension). Low blood pressure usually gets better within 30 minutes of the end of your ESMOCARD treatment.
- if you have a low heart rate before treatment.
- if your heart rate decreases to less than 50 to 55 beats per minute. If this happens your doctor may give you a lower dose or stop treatment with ESMOCARD.
- if you have heart failure or suffered from heart problems in the past. Your doctor will monitor you very closely for any symptoms of heart disease and if necessary, the treatment will be stopped, and the dosage lowered, or another treatment will be started.
- if you have problems with the electrical messages that control your heartbeat (first degree heart block).
- if you have a gland disease called phaeochromocytoma which has been treated with medicines called alpha-receptor blockers.
- if you are being treated for high blood pressure (hypertension) which has been caused by low body temperature (hypothermia).
- if you suffer from lung or breathing problems or wheezing, such as asthma or shortness of breath (dyspnoea), extra care will be taken when ESMOCARD is given to you.
- if you are a diabetic or have low blood sugar (hypoglycaemia). You will have to be monitored carefully as ESMOCARD can mask the symptoms of hypoglycaemia such as increased heartbeat. Other symptoms such as confusion and sweating are however not affected. ESMOCARD can increase the effects of your diabetes medicines.

- if you develop skin problems. If a skin reaction occurs where the injection is given another injection site will be used. Redness, burning pain or swelling at the administration site should be reported immediately.
- if you have a particular type of angina (chest pain) called 'Prinzmetal's angina'
- if you have low blood volume (with low blood pressure), you could develop circulatory collapse more easily. Do not use ESMOCARD if you are already taking similar medicine, as this may lead to blood loss during or after surgery.
- if you have circulation problems, such as paleness of your fingers (Raynaud's disease) or aching, tired and sometimes burning pains in your legs.
- if you suffer from kidney function impairment. If you have kidney disease or you need kidney dialysis you could develop high blood potassium levels (hyperkalemia). This can cause serious heart problems.
- if you have any allergies or are at risk of anaphylactic reactions (severe allergic reactions). ESMOCARD may increase your sensitivity toward allergens and the seriousness of an allergic reaction.
- if you or any of your family have a history of psoriasis (where your skin produces scaly patches).
- if you are on treatment with [β-] beta-blocker medicine (e.g. atenolol, propranolol etc) and/or have a disease called hyperthyroidism (an overactive thyroid gland).
- if you suffer from a disease called myasthenia gravis (an autoimmune neuromuscular disease leading to fluctuating muscle weakness and fatigue.

Children

Safety of use in children has not been tested.

Other medicines and ESMOCARAD

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

Tell your doctor if you are taking:

- medicines that can lower the blood pressure or slow the heart rate
- verapamil and diltiazem (calcium blocking medicines used to treat high blood pressure, heart rhythm problems or chest pain (angina)). You should not receive ESMOCARD within 48 hours of stopping verapamil.
- nifedipine (used to treat chest pain (angina), high blood pressure and Raynaud's disease)
- quinidine, disopyramide and amiodarone (medicines used for heart rhythm problems)
- insulin or other medicines used to treat diabetes
- general anaesthetics such as ether, cyclopropane and trichloroethylene
- ganglion blocking medicines (such as trimetaphan)
- non-steroidal anti-inflammatory drugs, known as NSAIDs (used as pain killers)
- floctafenine (pain killer)
- amisulpride (used to treat mental problems)
- tricyclic antidepressant medicines (such as imipramine and amitriptyline) or any other medicines for mental health problems
- barbiturates (such as phenobarbital, used to treat epilepsy)
- phenothiazines (such as chlorpromazine, used to treat mental disorders)
- clozapine (used to treat mental disorders)
- epinephrine (adrenaline), dopamine & norepinephrine (medicine used to treat anaphylactic shock – a serious allergic reaction)
- aminophylline or theophylline used in the treatment of asthma.
- reserpine (used to lower blood pressure)
- clonidine (used to treat high blood pressure and migraine)
- moxonidine (used to treat high blood pressure)
- ergot derivates (medicines mainly used to treat Parkinson's disease)
- warfarin (used to thin your blood)

- digoxin (used to treat heart failure) when given by injection
- morphine used to treat severe pain
- succinylcholine (also known as suxamethonium chloride or scoline) or mivacurium, used during anaesthesia to relax your muscles.

ESMOCARD with food and drink

Taking food and drink has no influence on your treatment with ESMOCARD.

Pregnancy, breastfeeding and fertility

ESMOCARD should not be used during pregnancy or breastfeeding, as the safety and effectiveness of ESMOCARD during pregnancy and breastfeeding have not been proven.

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 receiving ESMOCARD.

If you are given ESMOCARD during the last trimester of pregnancy (shortly before giving birth) or during labour or delivery, this may result in foetal bradycardia (an abnormally slow heartbeat of the foetus) and/or the newborn infant being born hypotonic (low muscle tone or decreased muscle strength), collapsed (state of physical weakness or extreme feebleness) and hypoglycaemic (low blood sugar levels).

There are no human data on the effects of ESMOCARD on fertility.

Driving and using machines

ESMOCARD may cause dizziness. Do not drive or operate machinery if you experience dizziness.

It is not always possible to predict to what extent ESMOCARD 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 ESMOCARD affects them.

ESMOCARD contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially 'sodium-free'.

3. How to use ESMOCARD

You will not be expected to give yourself ESMOCARD. It will be given to you by a person who is qualified to do so.

The duration of use depends on the effectiveness of treatment and possibly the occurrence of any side effects.

Your doctor will tell you how long your treatment with ESMOCARD will last.

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

Method of administration

ESMOCARD 100 mg/10 mL *(Single dose vial for infusion)* is pre-diluted to provide a ready-to-use 10 mg/mL concentration. ESMOCARD is given as an injection (infusion) and will be administered in a vein by a doctor or nurse.

ESMOCARD must not be mixed with sodium bicarbonate.

The treatment is given in two stages:

- Stage one: a large dose is given over one minute. This increases the levels in your blood quickly
- Stage two: a smaller dose is then given over four minutes
- Stage one and two may then be repeated and adjusted according to your heart’s response. As soon as an improvement has happened, stage one (the large dose) will be stopped and stage two (the small dose) will be reduced as necessary
- After reaching a stable condition, you may be given another heart medicine , while your dose of ESMOCARD is gradually reduced.

If your heart rate or blood pressure increases during an operation or straight after recovering from it, you will be given larger doses of ESMOCARD for a short time.

If you have received more ESMOCARD than you should

Since a healthcare professional will administer ESMOCARD, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The following symptoms may occur if too much ESMOCARD is given too rapidly: severe drop in blood pressure, slow heartbeat, heart block, reduced heart function (cardiogenic shock), cardiac arrest (heart attack), difficulty in breathing, loss of consciousness to coma, convulsions (seizures), nausea (feeling sick), vomiting (being sick), hypoglycaemia (low blood glucose levels) and hyperkalaemia (high blood potassium levels).

If you forget to use ESMOCARD

Since a health care provider will administer ESMOCARD, it is unlikely that the dose will be missed.

If you stop using ESMOCARD

Suddenly stopping ESMOCARD may cause symptoms of rapid heartbeat (tachycardia) and high blood pressure (hypertension) to return.

If you suffer from a heart disease caused by coronary artery problems (this may be associated with a history of angina or heart attack), caution is required when stopping ESMOCARD treatment. . To avoid this, the infusion will be stopped gradually.

If you have any further questions on the use of this medicine, please ask your doctor or healthcare provider.

4. Possible side effects

ESMOCARD can have side effects.

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

If any of the following happens, stop using ESMOCARD 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
- hives (urticaria), rash or itching
- fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- weight loss (anorexia)
- feeling depressed, anxious or nervous
- dizziness
- drowsiness (feeling sleepy)
- headache
- numbness and pins and needles feeling,
- difficulty concentrating
- confusion
- agitation
- low blood pressure
- nausea or vomiting (feeling or being sick)

- excessive sweating
- weakness
- tiredness
- irritation and hardening of your skin where ESMOCARD were injected.

Less frequent side effects:

- abnormal thinking
- fits (seizures or convulsions)
- speech disorder (problems with speech)
- problems with eyesight
- reduced heart rate and chest pain
- problems with the electrical messages that control your heartbeat
- increased pressure in the arteries of the lungs
- heart problems (inability of the heart to pump enough blood)
- a disruption in the rhythm of the heart sometimes known as palpitations (ventricular extrasystoles)
- a heartbeat disorder (nodal rhythm)
- chest discomfort caused by poor blood flow through the blood vessels of the heart muscle (angina pectoris)
- severe reduction in heart rate (sinus arrest)
- no electrical activity in the heart (asystole)
- narrowing of arteries that can result in skin ulceration and gangrene
- cold hands and feet
- pale skin
- flushing
- tender blood vessels with an area of hot red skin (thrombophlebitis)
- fluid accumulation in the lungs resulting in difficulty breathing

- wheezing, difficulty breathing
- blocked nose
- abnormal rattling/ crackling sounds when breathing
- changes in your sense of taste (taste perversion)
- indigestion
- constipation
- dry mouth
- pain in your stomach area
- skin discolouration
- reddening of the skin
- skin lesions due to the skin cell injury (necrosis)
- pain in your muscles or tendons, including around the shoulder blades and ribs
- muscle weakness
- lack of ability to urinate
- feeling cold or high temperature (fever)
- redness, pain and swelling at the injection site.
- burning or bruising at injection site.

Frequency unknown:

- increased levels of potassium in the blood (hyperkalemia)
- increased levels of acids in your body (metabolic acidosis)
- vivid dreams and nightmares
- seizures (generalised tonic-clonic)
- abnormal vision, dry eye
- increased rate of contraction of the heart (accelerated idioventricular rhythm)
- spasm of the artery in the heart

- failure of the normal circulation of the blood (cardiac arrest)
- low blood pressure without noticeable symptoms
- swelling of hands and feet
- abdominal discomfort
- psoriasis (where your skin produces scaly patches)
- inflammation of a vein or blistering at the site of infusion.

If you notice any other 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 "**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 ESMOCARD.

5. How to store ESMOCARD

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

Keep the container in the outer carton until required for use.

ESMOCARD should not be given to you after the expiry date shown on the pack.

ESMOCARD is a parenteral medicine which should be inspected visually for particulate matter and discolouration before administration, whenever the solution and container permit.

ESMOCARD 100 mg/10 mL is pre-diluted. Discard any unused portion after use.

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

6. Contents of the pack and other information

What ESMOCARD contains:

ESMOCARD 100 mg/10 mL contains as active ingredient 10 mg/mL esmolol hydrochloride. Each single dose vial of 10 mL contains 100 mg esmolol hydrochloride.

The other ingredients are acetic acid, hydrochloric acid, sodium acetate trihydrate and water for injection.

What ESMOCARD looks like and contents of the pack

A clear and colourless solution free of visible particles.

ESMOCARD 100 mg/10 mL: The solution is contained in a clear and colourless Type 1 glass vial closed with a grey serum rubber stopper with sealed with transparent ring flip-off seal packed into PVC tray or packed into blisters placed into cardboard box.

5 vials are placed together in one PVC tray or blister.

1 PVC tray or blister, containing 5 vials, per outer cardboard box.

Holder of Certificate of Registration

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