Applicant/PHRC: *Hetero Drugs South Africa (Pty) Ltd*

Product proprietary name: *DOBISIM*

Dosage form and strength: *Injection, Each 2 ml contains 20 mg lidocaine hydrochloride*

Each 5 ml contains 50 mg lidocaine hydrochloride

Each 30 ml contains 300 mg lidocaine hydrochloride

APPROVED PATIENT INFORMATION LEAFLET FOR DOBISIM

SCHEDULING STATUS

S4

DOBISIM strength pharmaceutical form

DOBISIM 2 ml solution for injection

DOBISIM 5 ml solution for injection

DOBISIM 30 ml solution for injection

Lidocaine (lignocaine) hydrochloride

Read all of this leaflet carefully before you are given DOBISIM.

- 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.

What is in this leaflet

1. What DOBISIM is and what it is used for

DOBISIM belongs to a group of medicines called local anaesthetics. DOBISIM injection can

be used in a number of different types of anaesthesia to "numb" part of the body, for example before surgery, to stop you feeling any pain.

2. What you need to know before you use DOBISIM

DOBISIM should not be administered to you:

- If you are hypersensitive (allergic) to lidocaine (lignocaine), local anaesthetics of the amide type or any of the other ingredients of DOBISIM (listed in section 6).
- If you suffer from complete heart block (a fault within your heart's natural pacemaker).
- If you suffer from a decreased blood volume (hypovolaemia).
- If you have any disturbances in the conduction of your heart.
- If you have bradycardia (a slow heart rate).
- If you have heart failure.
- If you have low blood pressure (characterised by dizziness or light-headedness).
- If you have a muscle disorder called myasthenia gravis

Warnings and precautions

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

- If you have epilepsy (fits).
- If you suffer from any liver disease or kidney problems.
- If you have porphyria (a rare inherited disease that affects the skin and nervous system)
- If you have an infection of the skin with pus at or near the site to be injected.
- If you have any breathing problems.
- If you are an elderly or weakened person.

The dose of DOBISIM should be reduced in children and the use of

DOBISIM is not recommended in neonates (newborns).

Other medicines and DOBISIM

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

The following may cause an interaction with DOBISIM:

- Mexiletine or amiodarone (used to treat irregular heartbeat).
- Suxamethonium (used to treat muscle spasms).
- Betablockers, e.g., timolol and propranolol (used to treat high blood pressure, irregular heartbeats and other conditions).
- Antidysrhythmics (used to treat heart rhythm disorders).
- Pimozide, sertindole, olanzapine, quetiapine or zotepine (used to treat schizophrenia).
- Tropisetron or dolansetron (used to treat nausea and vomiting following chemotherapy).
- Quinupristin or dalofopristin (used to treat certain serious bacterial infections).
- Acetazolamide (used to treat glaucoma).
- Loop diuretics (e.g., furosemide, used to treat heart failure).
- Thiazide diuretics (e.g., hydrochlorothiazide, used to treat high blood pressure).
- Cimetidine (used in to treat heartburn).
- Amprenavir, atazanavir, darunavir or lopinavir (used to treat human immunodeficiency virus (HIV) infection).
- Bupivacaine (used to provide anaesthesia during delivery to ease labour pain or other surgical procedures).
- Verapamil (used to treat high blood pressure, angina (chest pain) and certain heart rhythm disorders).

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 taking this medicine.

Driving and using machinery:

DOBISIM may affect your ability to drive a vehicle or operate machinery. Consult your doctor regarding when it would be safe to resume any activities requiring your attention.

DOBISIM contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Preservative free.

3.How to receive DOBISIM

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

DOBISIM will be given to you by a healthcare provider by injection, under the skin (subcutaneous) or into the muscle (intramuscular). Your healthcare provider will determine the correct dosage for you and how and when the injection will be given.

If you receive more DOBISIM than you should

Since a health care provider will administer DOBISIM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive DOBISIM

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

4. Possible side effects

DOBISIM can have side effects.

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

If any of the following happens, stop receiving DOBISIM and tell your healthcare provider immediately:

- '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 DOBISIM. 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:

- Dermatitis (red, swollen, sore or small blisters on skin).
- Breathing problems, coma.
- Seizures (fits).
- Heart problems (characterised by paleness, sweating, low blood pressure, heart rhythm disorders, slow heartbeat, heart arrest (characterised by loss of consciousness and abnormal or absent breathing).

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

Tell your doctor as soon as possible if you notice any of the following side effects:

Frequency not known:

- Stimulation of the central nervous system (characterised by yawning, feeling restless, excited, nervous, dizziness, light-headedness, shaking, tingling or tickling, blurred vision, nausea, vomiting, small muscle contraction).
- Depression, drowsiness.
- Numbness of the tongue and mouth area.
- Blood disorder (characterised by paleness, headache, difficulty in breathing, weakness).

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

Reporting side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reactions Form", found online under SAHPRA's publications: https://www.sahpra.org.za/publications/Index/8 / or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of DOBISIM.

5. How to store DOBISIM

- Store at or below 25 °C.
- Store container in original carton before and after use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Protect from light.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What DOBISIM contains

The active substance is:

Each 2 ml contains 20 mg lidocaine hydrochloride

Each 5 ml contains 50 mg lidocaine hydrochloride

Each 30 ml contains 300 mg lidocaine hydrochloride

The other ingredients are:

Sodium hydroxide, water for injection, sodium chloride, hydrochloric acid.

Preservative free.

What DOBISIM looks like and contents of the pack

DOBISIM 2 ml: 2 ml, Type I, tubular glass vial with 13 mm grey bromobutyl rubber stopper and 13 mm dark blue flip-off aluminium seal.1 vial or 21 vials in an outer carton.

DOBISIM 5 ml:5 ml, Type I, tubular glass vial with 13 mm grey bromobutyl rubber stopper and 13 mm Raymond blue flip-off aluminium seal.1 vial in an outer carton.

DOBISIM 30 ml:30 ml, Type I, tubular glass vial with 20 mm grey bromobutyl rubber stopper and 20 mm Raymond blue flip-off aluminium seal. 1 vial in an outer carton.

Holder of Certificate of Registration

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Registration Application number

DOBISIM 2 ml: 53/4/0164

DOBISIM 5 ml: 53/4/0165

DOBISIM 30 ml: 53/4/0166

Access to the corresponding Professional Information

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