PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BISLO 5 mg film-coated tablets

BISLO 10 mg film-coated tablets

Bisoprolol

Sugar free

Read all of this leaflet carefully before you start taking BISLO

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

1. What BISLO is and what it is used for

BISLO contains the active ingredient bisoprolol fumarate. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart.

BISLO is used to treat high blood pressure and recurring angina pectoris.

2. What you need to know before you take BISLO

Do not take BISLO if:

- You are hypersensitive (allergic) to bisoprolol or any of the other ingredients of BISLO **(**listed in section 6).
- You suffer from acute heart failure or if you are receiving therapy for a weak heart.
- You have a weak, irregular or slow heartbeat.
- You have low blood pressure.
- You suffer from severe asthma or from other severe breathing difficulties, such as chronic obstructive lung disease.
- You suffer from metabolic acidosis, a condition where there is too much acid in your blood (this sometimes occurs as an acute complication of diabetes).
- You suffer from severe blood circulation problems in your limbs, including severe forms of Raynaud's syndrome (a condition where the blood supply to the tips of your fingers or toes may become restricted which may cause tissue damage).
- You suffer from untreated phaeochromocytoma, a rare tumour of the adrenal glands (marked by high blood pressure, raised heart rate and headache).
- You are pregnant or breastfeeding (see **Pregnancy and breastfeeding**).
- You have a thyroid problem; BISLO can hide the symptoms of an overactive thyroid (characterised by weight loss, increased appetite, sweating or rapid heart rate).

Warnings and precautions

Take special care with BISLO:

- If you suffer from diabetes mellitus (low blood sugar levels may be masked by BISLO).

- If you suffer from an irregular heartbeat, or from circulatory problems: less severe forms of Raynaud's syndrome (resulting in temporary discolouration of your skin and numbness of your fingers or toes).
- If you experience sudden onset of chest pain, or if you already suffer from a mild form of angina (chest pain).
- If you suffer from phaeochromocytoma, a rare tumour of the adrenal gland (marked by high blood pressure, raised heart rate and headache), these conditions should be treated first, prior to taking BISLO.
- If you suffer from (or have suffered) from psoriasis (marked by severe recurring skin rashes).
- If you are due to have an operation, you should inform the doctor that you are taking BISLO.
- If you are fasting from solid food.
- If you are being treated for hypersensitivity (allergic) reactions. BISLO may make your allergy worse or more difficult to treat.
- If you have kidney problems, your doctor may adjust your BISLO dose.
- If you are taking any medicine to control the way your heart beats.
- If you are planning to stop your treatment with BISLO. BISLO should be discontinued gradually and your doctor will instruct you on how to stop your treatment with BISLO.
- If you suffer from asthma or any other chronic lung disease.

Children and adolescents

Safety and efficacy in children have not been established.

Other medicines and BISLO

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

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

- Calcium channel blockers, such as verapamil or diltiazem (used to treat high blood pressure), as

you may experience changes in the way your heart beats when taking BISLO with these medicines.

- Antidysrhythmic medicines, such as amiodarone, quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone (used to treat an irregular or rapid heartbeat), as you may develop myocardial depression (depression of the heart muscle).
- Certain antihypertensives acting in the brain, such as clonidine, alpha-methyldopa and moxonidine (used to treat high blood pressure), as it may reduce your heart rate and contractions. Sudden withdrawal of these medicines may cause a sudden increase of blood pressure.
- Certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists, such as felodipine and amlodipine).
- Oral blood sugar lowering medication or insulin, as you may experience extremely low blood sugar levels when taking BISLO with these medicines.
- Medicines in the beta-adrenoceptor agonist class, such as dobutamine (used to treat heart failure) or isoprenaline (used to treat a slow heart rate) which may antagonise the effects of BISLO.
- Medicines in the alpha-adrenoceptor agonist class, such as phenylephrine or pseudoephedrine (used as nasal decongestants), as they may decrease the effects of BISLO.
- Reserpine (used to treat high blood pressure), as use with BISLO may cause life-threatening vasoconstriction (constricting of the blood vessels).
- Digoxin (used to improve the strength and efficiency of the heart or control the rate and rhythm of the heart) may be used with BISLO. Your doctor should monitor your pulse rate and response regularly.
- Parasympathomimetic medicine (used to stimulate the nervous system), as it may interfere with the way your heart beats.
- Mefloquine (used to prevent/treat malaria), as you may experience a slow heart rate when taking it with BISLO.
- Beta-blocker eye drops (used to treat certain eye conditions), which may cause more side effects to occur.

- Anaesthetic medicines (used for anaesthesia during an operation), which may cause an increase in your heart rate or cause low blood pressure. If you are due to have an operation, tell the anaesthetist or the medical staff that you are taking BISLO.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat pain), as it may reduce the efficacy of BISLO.
- Rifampicin (used to treat tuberculosis [TB]) and barbiturates (used as tranquillisers), which may increase the metabolism of BISLO.
- Erythromycin (used to treat bacterial infections), which may decrease the metabolism of BISLO.
- Any medicine which can lower blood pressure, such as antihypertensives (including angiotensin-enzyme converting [ACE] inhibitors), certain medicines for depression (tricyclic antidepressants, such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates, such as phenobarbital), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines, such as levomepromazine).
- Monoamine oxidase inhibitors (except MAO-B inhibitors), such as moclobemide (used to treat depression).

BISLO with food or drink

See section 3.

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 BISLO. Do not use BISLO if you are pregnant, suspect that you are pregnant or breastfeeding (see **What you need to know before you take BISLO**).

Driving and using machines

BISLO may make you drowsy, especially when starting treatment with BISLO or when using alcohol. Caution is advised before driving or using machines until you know how BISLO affects you.

3. How to take BISLO

Do not share medicines prescribed for you with any other person.

Always take BISLO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

You and your doctor should talk about the benefits and risks of treatment with BISLO.

Adults:

The dose of BISLO will be different for each patient, and may depend on what the medicine is being used for, your age and if other medicines are also being given or taken at the same time.

The normal dose is 10 mg daily.

In some patients 5 mg daily will be adequate. The maximum recommended dose is 20 mg daily.

Your doctor will advise you what the best dosage is for you.

BISLO can be taken with or without food.

The tablets should be taken at approximately the same time each day.

If you have kidney problems, please tell your doctor. If you have any questions about the proper dose of BISLO, ask your doctor.

Your doctor will tell you how long your treatment with BISLO will last. You should not stop taking BISLO suddenly. Your doctor will tell you how to do it.

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

If you take more BISLO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining tablets with you so the doctor will know what you have taken.

If you forget to take BISLO

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take BISLO at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking BISLO

BISLO should be discontinued gradually to avoid side effects, and your doctor will instruct you on how to stop your treatment with BISLO.

4. Possible side effects

BISLO can have side effects.

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

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

- swelling of your 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 BISLO. 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:

- yellowing of your skin and eyes, also called jaundice or liver toxicity,
- chest pain,
- heart problems or changes in the way your heart beats (skipping beats or beating slower than normal),
- signs of recurrent infections, such as fever or sore throat,
- unexplained bleeding or bruising, such as bleeding gums, nose or pinpoint bleeds on your skin,
- reduced blood flow, Raynaud's phenomenon or gangrene (discolouration, numbness, coldness or pain of your fingers or toes),
- difficulty breathing or lung disease,
- severe high blood pressure,
- low blood sugar (anxiety, sweating, nausea or heart palpitations).

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:

- drowsiness, trouble in sleeping, unusual tiredness or weakness,
- low blood pressure,
- decreased sexual ability,
- inability to get and maintain an erection,
- headache (these are generally mild, especially at the beginning of therapy, and often disappear within 1 – 2 weeks),
- nausea, vomiting, diarrhoea, constipation,
- dizziness.
- weight gain.

Less frequent side effects:

- anxiety and/or nervousness,
- feeling depressed or confused,
- hallucinations (seeing or hearing things that are not real),
- nasal congestion (blocked or runny nose),
- dry, sore eyes,
- conjunctivitis (red, itchy, burning eyes with a white or green discharge or thick yellow discharge),
- nightmares and vivid dreams,
- sudden drop in your blood pressure when you get up from a sitting or lying position (dizziness or light-headedness), fainting,
- back pain or joint pain,
- hair loss (temporary),
- activating or worsening of psoriasis (red, dry, flaky skin rash),
- muscle cramps or weakness.

Side effects with an unknown frequency

- high cholesterol,
- increased levels of uric acid in your blood (gout),
- restlessness,
- paraesthesia (tingling, burning or numb sensation of your skin),
- psychosis (abnormal thinking, losing contact with reality),
- problems with your vision,
- loss of hearing,
- fluid retention,
- inflammation of your gums,
- sweating.

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 "**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 BISLO.

5. How to store BISLO

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after expiry date printed on the blister 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 BISLO contains

The active substance is bisoprolol fumarate.

BISLO 5: Each tablet contains 5 mg bisoprolol fumarate.

BISLO 10: Each tablet contains 10 mg bisoprolol fumarate.

The other ingredients are colloidal silicon dioxide, crospovidone, dibasic calcium phosphate anhydrous, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate, pregelatinised starch and titanium dioxide (E171).

BISLO 5: Ferric oxide red and ferric oxide yellow.

What BISLO looks like and contents of the pack

BISLO 5: Salmon pink coloured, biconvex, round, film-coated tablet, debossed with ‘UL’ on one side and break line on the other side, with ‘5’ debossed on either side of the break line.
BISLO 10: White coloured, biconvex, round, film-coated tablet, debossed with ‘UL’ on one side and ‘10’ on other side.

Transparent clear PVC/PVDC/aluminium foil blister strips containing 10 tablets each. Three (3 x 10) blister strips are packed in an outer carton.

Holder of certificate of registration

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