

Product Name: **BISOPROLOL UNICORN 5 & 10**
Applicant Name: Unicorn Pharmaceuticals (Pty) Ltd.
Product Strength and dosage form: 5 mg, 10 mg bisoprolol fumarate

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BISOPROLOL UNICORN 5 tablets

BISOPROLOL UNICORN 10 tablets

5 mg, 10 mg bisoprolol fumarate

Contains sugar (135,20 mg, 130,20 mg) lactose monohydrate)

Read all of this leaflet carefully before you start taking **BISOPROLOL UNICORN**

- 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.
- **BISOPROLOL UNICORN** 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 **BISOPROLOL UNICORN** is and what it is used for
2. What you need to know before you take **BISOPROLOL UNICORN**
3. How to take **BISOPROLOL UNICORN**
4. Possible side effects
5. How to store **BISOPROLOL UNICORN**
6. Contents of the pack and other information

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1. What **BISOPROLOL UNICORN** is and what it is used for

BISOPROLOL UNICORN contains the active substances bisoprolol fumarate. Bisoprolol fumarate belongs to a group of medicines called beta-blockers. Beta-blockers protect the heart against too much activity. This medicine works by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol fumarate slows down the heart rate and makes the heart more efficient at pumping blood around the body. Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's need.

BISOPROLOL UNICORN is used for the management of mild to moderate high blood pressure and recurring angina pectoris. Angina pectoris is a disease in which the cardiac muscles receive less oxygen than is necessary. This generally occurs during exercise and the most common symptom is chest pain caused by blockages in the arteries that supply the heart muscle.

2. What you need to know before you take **BISOPROLOL UNICORN**

Do not take BISOPROLOL UNICORN if:

- You are hypersensitive (allergic) to bisoprolol fumarate or any of other the ingredients in **BISOPROLOL UNICORN** (see section 6).
- You suffer from severe asthma or from other breathing difficulties.
- You suffer from late stage peripheral arterial occlusive disease, including severe forms of Raynaud's syndrome (a condition where the blood supply to the tips of the fingers or toes may become restricted as to cause tissue damage).
- You have a weak, irregular heartbeat or slow heart rate.
- You have heart block, where the heart beats very slowly.
- You have uncontrolled heart failure.

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- You suffer from acute heart failure or if you are receiving therapy for a weak heart.
- You have a heart condition in which your heart suddenly can't pump enough blood to meet your body's needs.
- You suffer from metabolic acidosis (this sometimes occurs as an acute complication of diabetes).
- You have low blood pressure.
- You have been diagnosed with a condition known as sick sinus syndrome (a group of abnormal heart rhythms presumably caused by a malfunction of the heart's primary pacemaker).
- You suffer from phaeochromocytoma, a rare tumour of the adrenal gland (medulla) (marked by high blood pressure, raised heart rate and headache).
- If you suffer from a condition marked by excessive production of thyroid hormones.
- It is to be given to a child.
- If you are pregnant.

Warnings and precautions

Take special care with BISOPROLOL UNICORN:

- If you are due to receive an anaesthetic e.g. before an operation; you should inform the hospital doctor that you are taking **BISOPROLOL UNICORN**. This medicine may influence how your body react to this situation.
- If you suffer from an irregular heartbeat, you experience sudden onset of chest pain, or if you already suffer from a mild form of angina or Prinzmetal's angina.
- If you have any heart problems or first degree heart block (a condition in which nerve signals to the heart are disturbed, possibly causing it occasionally to skip a beat, or beat irregularly).
- If you are elderly (over the age of 60 years).

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- If you have liver or kidney problems.
- If you are using medicines (verapamil or diltiazem) to treat an irregular heartbeat.
- If you suffer from diabetes mellitus (low blood sugar levels may be masked by this medicine).
- If you suffer from phaeochromocytoma (marked by high blood pressure, raised heart rate and headache); this condition should be treated first, prior to taking **BISOPROLOL UNICORN**.
- If you are using a medicine that contains clonidine (used to treat high blood pressure).
- If you suffer from or have suffered from psoriasis (marked by severe skin rashes).
- If you are fasting from solid food.
- If you have a thyroid disorder. The tablets can hide symptoms of an overactive thyroid.
- If you are going to have desensitization therapy (e.g. to prevent hay fever), tell your healthcare professional since **BISOPROLOL UNICORN** may make it likely that you will experience an allergic reaction, or more severe reaction.
- If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using **BISOPROLOL UNICORN**.
- If you have any problems with the circulation in your limbs.
- If you are treated for hypersensitivity (allergic) reactions. Bisoprolol may make your allergy worse or often difficult to treat.

Do not stop **BISOPROLOL UNICORN** therapy abruptly, especially if you have coronary heart disease as this may lead to transitional worsening of your heart condition.

Children and adolescents

Bisoprolol fumarate is not recommended for use in children or adolescents. Safety and

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efficacy of **BISOPROLOL UNICORN** have not been established in children.

Other medicines and BISOPROLOL UNICORN

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

- You may experience extremely low blood sugar levels when taking **BISOPROLOL UNICORN** with oral blood sugar lowering medication or insulin.
- You may have myocardial depression (depression of the heart muscle) when taking antidysrhythmic medicines, such as amiodarone (used to treat an irregular or rapid heartbeat).
- Medicines used to treat acute heart problems (such as isoprenaline, dobutamine) may antagonise the effects of **BISOPROLOL UNICORN**.
- Sympathomimetics such as epinephrine and norepinephrine which are used in the treatment of heart attack and low blood pressure. Epinephrine is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for treatment of allergic reactions if **BISOPROLOL UNICORN** is taken at the same time.
- Medicines used to treat high blood pressure (such as clonidine, digitalis, glycosides, diltiazem, methyldopa, moxonodine and rilmenidine) may further decrease heart rate when taken with **BISOPROLOL UNICORN**. However, do not stop taking these medicines without checking with your doctor first.
- Using certain medicines (such as reserpine or guanethidine) causing high blood pressure together with **BISOPROLOL UNICORN** may cause life-threatening vasoconstriction (constricting of the blood vessels).
- Digoxin (used to treat heart failure or control the rate and rhythm of the heart) may be used with **BISOPROLOL UNICORN**. Your doctor should monitor your pulse rate and response regularly.

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- Certain medicines used to treat mental illness e.g. phenothiazines.
- Dihydropyridine-type calcium antagonists, such as nifedipine and amlodipine, used to treat high blood pressure or angina pectoris.
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (known as Calcium antagonists of the verapamil type).
- Medicines used to treat irregular or abnormal heartbeat, such as disopyramide, feldopine, flecainide, propafenone or quinidine.
- Medicines used to treat conditions such as Alzheimer's disease or glaucoma (known as parasympathomimetics) such as tacrine or carbachol.
- Beta-blockers applied locally (such as timolol eye drops to treat glaucoma).
- Non-steroidal anti-inflammatory medicines (NSAID's) used to treat arthritis, pain or inflammation (e.g. ibuprofen or diclofenac,). These medicines may reduce the effects of **BISOPROLOL UNICORN.**
- Medicines which can result in the lowering of blood pressure (e.g. medicines specifically given to lower blood pressure, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), during anaesthesia (lidocaine) or epilepsy (phenytoin or barbiturates such as phenobarbital).
- Moxisylyte which is used to treat circulatory problems like Raynaud's syndrome.
- Halofantrine, mefloquine and quinine used for the prevention or treatment of malaria.
- The effects of **BISOPROLOL UNICORN** may be increased when taken with monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.
- Rifampicin, an antibiotic used to treat infections, including tuberculosis (TB).
- Ergotamine derivatives used in the acute treatment of migraine headaches.
- Anaesthetics (for example medicines used during surgery). If you are due to have an operation, tell the anaesthetist or the medical staff you are taking **BISOPROLOL UNICORN.**

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- Medicines for asthma or medicines used for a blocked nose.

BISOPROLOL UNICORN with food, drink and alcohol

The tablets can be taken with or without food but must be taken in the morning.

Do not drink alcohol whilst taking **BISOPROLOL UNICORN** as it could cause your blood pressure to fall too low.

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 **BISOPROLOL UNICORN**.

BISOPROLOL UNICORN is not recommended during pregnancy and breastfeeding.

Driving and using machines

BISOPROLOL UNICORN may cause dizziness, drowsiness or muscle cramps. Please make sure you know how **BISOPROLOL UNICORN** affects you before driving or using machinery.

It is not always possible to predict to what extent **BISOPROLOL UNICORN** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **BISOPROLOL UNICORN** affects you.

BISOPROLOL UNICORN contains sugar (lactose).

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **BISOPROLOL UNICORN**.

BISOPROLOL UNICORN contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have intolerance to some sugars, contact your

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doctor before taking **BISOPROLOL UNICORN**.

3. How to take BISOPROLOL UNICORN

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

Always take **BISOPROLOL UNICORN** exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of **BISOPROLOL UNICORN** is too strong or too weak for you, tell your doctor or pharmacist.

Treatment with Bisoprolol fumarate tablet requires regular medical check up. This is particularly important in the initiation of therapy and during dose increase.

Adults:

The usual dose is 5 mg once daily.

If necessary, the dosage may be increased to 10 mg once daily

The maximum recommended dose is 20 mg per day.

Chest pain and high blood pressure:

Your doctor will start the treatment with lowest possible dose (5 mg). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you.

The maximum recommended dose is 20 mg once per day.

Patient with kidney disease:

In patients with mild to moderate kidney disease or that are on dialysis, adjustment of the dose is not normally needed.

Patients with severe kidney disease should not exceed 10 mg of bisoprolol once daily.

Please consult your doctor before starting to use this medicine.

Patient with liver disease:

In patients with mild to moderate liver disease, adjustment of the dose is not normally

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needed.

Patients with severe liver disease should not exceed 10 mg of bisoprolol once daily. Please consult your doctor before starting to use this medicine.

The dose of Bisoprolol Fumarate will be increased gradually until the dose that is suitable for you has been found:

Treatment with Bisoprolol fumarate tablet must be started at a low dose and increased gradually. Your doctor will decide how to increase the dose, and this will normally be done in the following way:

Bisoprolol Fumarate is not recommended for use in children or adolescents.

Elderly patient:

In general, adjustment of the dose is not needed. It is recommended to start with lowest possible dose.

If you notice that the effect of Bisoprolol Fumarate is too strong or not strong enough, please consult your doctor or pharmacist.

The tablets should be swallowed whole with some liquid in the morning with or without food.

BISOPROLOL UNICORN is not indicated for use in children.

BISOPROLOL UNICORN therapy should not be stopped abruptly.

Your doctor will tell you how long your treatment with **BISOPROLOL UNICORN** will last.

If you take more BISOPROLOL UNICORN than you should

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

If you have taken too much **BISOPROLOL UNICORN** you may experience the following: a slowed heart rate, severe difficulty in breathing, wheezing, feeling dizzy, fatigue or trembling (due to decreased blood sugar which may involve feelings of hunger, sweating and palpitations). Heart problems, coma and convulsions have also been reported.

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If you forget to take BISOPROLOL UNICORN

Take the missed dose of **BISOPROLOL UNICORN** as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time.

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

If you stop taking BISOPROLOL UNICORN

If you have to stop **BISOPROLOL UNICORN** treatment early, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

4. Possible side effects

BISOPROLOL UNICORN can have side effects.

Not all side effects reported for **BISOPROLOL UNICORN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **BISOPROLOL UNICORN**, please consult your healthcare provider for advice.

If any of the following happen, stop taking **BISOPROLOL UNICORN** and tell your doctor immediately or go to the causality department at your nearest hospital:

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

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

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

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- Slow pulse rate, irregular heartbeats or changes to your heart rate which may cause dizziness and weakness.
- Worsening of heart failure which can cause a persistent chesty cough due to a build-up of fluid on the lungs.
- Worsening of symptom of blockage of the main blood vessel to the legs, especially at the start of treatment

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

Tell your doctor if you notice any of the following:

Side effects that may occur frequently include:

- Drowsiness, unusual tiredness or weakness.
- Decreased sexual ability.
- Feeling of coldness or numbness in hands or feet.
- Low blood pressure (you may feel light-headed).
- Headache, dizziness and extreme tiredness (these may be mild especially at the beginning of therapy and may often disappear within 1 - 2 weeks).
- Nausea, vomiting, diarrhoea, constipation.
- Lack of energy.

Less frequent side effects that may occur include the following:

- Loss of memory, confusion, hallucinations, depression, trouble sleeping, nightmares and vivid dreams, anxiety and/or nervousness.
- Allergic runny nose, sneezing and itching, nasal congestion, breathing problems in patients with asthma, chronic lung disease or other problems of the airways.
- Dry, sore eyes, irritation and redness of the eye (conjunctivitis),
- Reduced tear flow which may lead to problems if you wear contact lenses.
- Skin rash, itching of the skin, appearance or worsening of scaly skin rash (psoriasis).

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- Back pain, joint pain or chest pain, muscle cramps, muscle weakness.
- Dizziness on standing, fainting.
- Hearing problems.
- Raynaud's syndrome (a condition where the blood supply to the tips of the fingers or toes may become restricted so as to cause tissue damage).
- Blue fingers and toes.
- Inflammation of the liver which can cause yellowing of the skin or the whites of the eyes and skin and dark urine.
- Hair-loss (which will grow back after treatment with **BISOPROLOL UNICORN** is stopped).
- Impaired erection.
- Physical weakness or lack of energy
- Certain blood test results for liver function or fat levels differing from normal.

Side effects that may occur, but with unknown frequency, include the following:

- Systemic Lupus Erythematosus (also known as 'lupus' or 'SLE') a disease characterised by inflammation and damage to various body tissues.
- Restlessness, loss of contact with reality.
- Problem seeing.
- Temporary loss of hearing.
- Fluid retention.
- Inflammation, excessive fibrous connective tissue or fluid in the lungs leading to breathing difficulties or a sharp stabbing pain in the chest.
- Stomach cramps, dry mouth, weight gain, inflammation of the mouth or lips.
- Sweating, irritation of the skin.
- Pins-and-needles sensation.

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Side effects are more common in patients with kidney problems.

If treated for high blood pressure or angina then these symptoms occur especially at beginning of treatment, or if your dosage changes. They are generally mild or often disappear within 1 to 2 weeks.

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 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 **BISOPROLOL UNICORN**. Reporting can also be done directly to Unicorn Pharmaceuticals at: vigilance@unicornpharma.co.za.

5. How to store BISOPROLOL UNICORN

Store at or below 25 °C.

Protect from light.

Keep the blister in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 BISOPROLOL UNICORN contains

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BISOPROLOL UNICORN 5:

The active substance: Each tablet contains 5 mg bisoprolol fumarate.

BISOPROLOL UNICORN 10:

The active substance: Each tablet contains 10 mg bisoprolol fumarate.

The other ingredients in BISOPROLOL UNICORN are: Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose and iron oxide yellow (the colorant for **BISOPROLOL UNICORN 5**) or iron oxide beige (the colorant for **BISOPROLOL UNICORN 10**).

Contains sugar (135,20 mg, 130,20 mg) lactose monohydrate).

What BISOPROLOL UNICORN looks like and contents of the pack

BISOPROLOL UNICORN 5: Mottled pale yellow, round normal convex tablet debossed with 'BI' break line '5' on one side and plain on the reverse.

BISOPROLOL UNICORN 10: Mottled beige, round normal convex tablet debossed with 'BI' break line '10' on one side and plain on the reverse.

Opaque or clear Al/PVC/PVdC blister packs containing 30 tablets.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd.

Corner Searle and Pontac Streets

Woodstock

Cape Town

8001

South Africa

enquiries@unicornpharma.co.za

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