PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BISOPROLOL CO UNICORN 5/6,25 TABLETS

BISOPROLOL CO UNICORN 10/6,25 TABLETS

Bisoprolol fumarate and hydrochlorothiazide

Sugar free.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BISOPROLOL CO 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 CO UNICORN** is and what it is used for

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

3. How to take **BISOPROLOL CO UNICORN**

4. Possible side effects

5. How to store **BISOPROLOL CO UNICORN**

6. Contents of the pack and other information

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

BISOPROLOL CO UNICORN is used to treat high blood pressure.

2. What you need to know before you take BISOPROLOL CO UNICORN:

Do not take BISOPROLOL CO UNICORN if:

- You are hypersensitive (allergic) to bisoprolol or to any of the other ingredients of **BISOPROLOL CO UNICORN** or other sulphonamide derived medicines (see **WHAT BISOPROLOL CO UNICORN CONTAINS**).
- If you or anyone in your family have a history of previous and/or current cancer of the skin and lip.
- You suffer from uncontrolled heart failure or if you are receiving therapy for a weak heart.
- You have problems with a very slow heart beat or a heart block.
- You have cardiogenic shock which is a heart condition causing low blood pressure and circulatory failure.
- You have very low blood pressure.
- You suffer from asthma or from another disease causing severe breathing difficulties.
- You suffer from metabolic acidosis, a condition in which the blood is too acidic.
- You suffer from a condition marked by excessive production of thyroid hormones.
- You suffer from severe blood circulation problems in your limbs (such as Raynaud's syndrome which may cause your fingers and toes to tingle or turn pale or blue).
- You suffer from untreated phaeochromocytoma, which is a tumour of the adrenal gland.

- You have Addison's disease (your adrenal glands do not produce enough of their hormones).
- You are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**).
- You suffer from severe kidney or liver problems.
- You have porphyria (a disorder that affects how your body makes red blood cells).

Warnings and precautions

Take special care with BISOPROLOL CO UNICORN:

- If you are taking quinidine, as the combination of **BISOPROLOL CO UNICORN** with quinidine may cause life-threatening abnormal heart rhythms.
- If you suffer from any breathing difficulties.
- If you suffer from diabetes and are taking anti-diabetic medicines, such as insulin, you should regularly check your blood for low blood glucose levels. Signs of low blood sugar, such as fast heartbeat, may be masked by **BISOPROLOL CO UNICORN**.
- If you are taking certain medicines to treat irregular heartbeat, angina pectoris (chest pain on exertion) or to treat high blood pressure (e.g. disopyramide, clonidine, myocardial depressants or calcium antagonists, such as verapamil).
- If you experience sudden onset of chest pain, or if you already suffer from a mild form of angina.
- If you have been prescribed **BISOPROLOL CO UNICORN** and suffer from phaeochromocytoma (a tumour of the adrenal gland); this condition should be treated first, prior to taking **BISOPROLOL CO UNICORN**.
- If you suffer from psoriasis (marked by severe skin rashes).

- If you are due to have an operation. Tell the anaesthetist or the medical staff you are taking **BISOPROLOL CO UNICORN** tablets at least 48 hours before the operation.
- If you are wearing contact lenses, as **BISOPROLOL CO UNICORN** may decrease tear flow, causing eye irritation.
- If you previously experienced an allergic reaction to penicillin, or other medicines containing sulphonamides. **BISOPROLOL CO UNICORN** can cause eye problems that, if left untreated, may lead to vision loss; especially in patients with a history of allergy to penicillin and sulphonamides. Symptoms of eye problems can happen within hours to weeks of starting treatment.

Tell your doctor immediately if you have:

- Decrease in vision.
- Eye pain.
- If you have a history of allergies, since **BISOPROLOL CO UNICORN** may make it more likely that you develop an allergic reaction, or that such a reaction is more severe.
- If you suffer from kidney or liver problems.
- If you have high calcium levels in your body.
- If you have had gout.
- If you want to stop taking **BISOPROLOL CO UNICORN**. You must discuss this with your doctor first. You should stop taking **BISOPROLOL CO UNICORN** gradually and limit your amount of exercise during this period. Your doctor will guide you.
- If you previously had skin cancer or if you develop an unexpected skin lesion during treatment. Treatment with hydrochlorothiazide, particularly long-term use with high

doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays
while taking **BISOPROLOL CO UNICORN**.

DO NOT give **BISOPROLOL CO UNICORN** to children younger than 12 years as safety and efficacy have not been established.

Other medicines and BISOPROLOL CO UNICORN

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

- You may experience extremely low blood sugar levels when taking **BISOPROLOL CO UNICORN** with oral blood sugar lowering medication or insulin.
- You may have impaired myocardial function (problems of the heart muscle or a heart block) when taking antidysrhythmic medicines used to treat an irregular or rapid heartbeat (such as lidocaine, quinidine, disopyramide, flecainide and propafenone), calcium channel blockers (such as verapamil or diltiazem) or phenothiazines (used for mental illness).
- You may experience a worsening of heart failure if you take **BISOPROLOL CO UNICORN** with other medicines to treat high blood pressure, such as methyldopa.
- Medicines in the beta-adrenoceptor agonist class (such as dopamine, dobutamine and isoprenaline) may alter the effects of **BISOPROLOL CO UNICORN**.
- Nasal decongestants (to open a blocked nose) used for colds, such as phenylephrine, pseudoephedrine or phenylpropanolamine, may increase your blood pressure.

- Using reserpine with **BISOPROLOL CO UNICORN** may cause life-threatening vasoconstriction (constricting of the blood vessels causing an increase in blood pressure).
- Digoxin (used to improve the strength and efficiency of the heart or control the rate and rhythm of the heart) may be used with **BISOPROLOL CO UNICORN**. Your doctor should monitor your pulse rate and response regularly.
- When **BISOPROLOL CO UNICORN** is used for a prolonged time with medication such as corticosteroids, you may have an increased risk of developing low blood potassium levels. If your blood potassium levels are low, you may develop weakness, confusion and mental depression. You need to inform your doctor immediately if you experience such symptoms.
- Anti-inflammatory medication (NSAID painkillers, such as indomethacin) may reduce the blood pressure lowering effects of **BISOPROLOL CO UNICORN** and may cause sodium and water retention with possible swelling of your feet, ankles, hands and/or face.
- Low salt content in the body may occur in patients taking trimethoprim (an antibiotic) or carbamazepine (for nervous system related conditions) with **BISOPROLOL CO UNICORN**.

BISOPROLOL CO UNICORN with food and drink:

The tablets can be taken with or without food.

BISOPROLOL CO UNICORN taken together with alcohol may cause dizziness or light-headedness.

Pregnancy and Breastfeeding and Fertility:

DO NOT take **BISOPROLOL CO UNICORN** if you are pregnant, plan to become pregnant, or suspect that you are pregnant. Contact you doctor or healthcare professional immediately.

DO NOT take **BISOPROLOL CO UNICORN** during breastfeeding.

Administration of **BISOPROLOL CO UNICORN** to pregnant mothers shortly before giving birth or during labour may result in the baby being born with low blood sugar, low muscle tone and/or a slow heartbeat.

Driving and using machines:

BISOPROLOL CO UNICORN may make you feel drowsy or dizzy. Therefore, please make sure you know how **BISOPROLOL CO UNICORN** affects you before driving or using machinery.

3. HOW TO TAKE BISOPROLOL CO UNICORN:

Always take **BISOPROLOL CO UNICORN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

Therapy may be initiated with the lowest dose of bisoprolol/hydrochlorothiazide 2,5/6,25 mg, taking one tablet per day. Another formulation should be used. Subsequent dose adjustment may be carried out with **BISOPROLOL CO UNICORN** tablets up to the maximum recommended dose of one 10/6,25 mg tablet once daily as appropriate. The tablets should be taken at about the same time each day.

If you have any questions about the proper dose of **BISOPROLOL CO UNICORN**, ask your doctor.

Treatment with **BISOPROLOL CO UNICORN** should not be stopped abruptly.

BISOPROLOL CO UNICORN should not be given to children less than 12 years old (see **Take special care with BISOPROLOL CO UNICORN**).

If you take more BISOPROLOL CO UNICORN than you should:

In the event of overdosage, consult your doctor or pharmacist; if neither is available, contact 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 forget to take BISOPROLOL CO UNICORN:

Take the missed dose 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.**

4. POSSIBLE SIDE-EFFECTS:

BISOPROLOL CO UNICORN may have side-effects. Not all side-effects reported for **BISOPROLOL CO UNICORN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effect while taking **BISOPROLOL CO UNICORN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking BISOPROLOL CO UNICORN and contact your doctor or healthcare professional immediately:

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

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to BISOPROLOL CO UNICORN. You may need urgent medical attention or hospitalisation. All of these are very serious side-effects, but are less frequently encountered.

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

- Chest pain.
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Difficulty breathing.
- Discoloration of the skin and numbness of the fingers or toes.
- Unusual bruising and nosebleeds, or bleeding in the mouth and gums.
- Yellowing of the skin and whites of the eyes, also called jaundice..
- Changes to your skin (new growths or lesions) as this could be a sign of skin cancer.

These are all serious side-effects. You may need urgent medical attention. Serious side-effects occur less frequently.

Side-effects that may occur more frequently include:

- Drowsiness, trouble in sleeping, unusual tiredness or weakness.
- Low amount of platelets in the blood, or reduced amount of salt in the body.

- Decreased sexual ability.

Less frequent side-effects that may occur include the following:

- Blood cell disorders.
- Increase or decrease of sugar in the blood, or sugar in the urine .
- Gout (an increase of uric acid in the body).
- Inflammation of the pancreas or infection of the salivary glands .
- Inflammation of the lining of the mouth.
- Loss of appetite (anorexia), increase in weight.
- Anxiety and/or nervousness.
- Nightmares and vivid dreams, depression .
- Hallucinations (hearing or seeing things that are not there).
- Dizziness, headache, restlessness.
- Extreme tiredness.
- Tingling or numbness of limbs.
- Feeling dizzy when standing, fever.
- Dry, sore eyes, reduced tear flow.
- Blurred vision or seeing objects more yellow than they are.
- Temporary loss of hearing.
- Blocked nose.
- Nausea, vomiting, diarrhoea, abdominal pain, constipation.
- Skin rash, sensitivity of skin to the sun, sweating, loss of hair.
- Back pain or joint pain, muscle cramps or muscle weakness.
- Kidney problems.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 CO UNICORN**.

Adverse reactions must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za

5. How to store BISOPROLOL CO UNICORN:

- Store at or below 30 °C.
- Keep the blisters 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

BISOPROLOL CO UNICORN 5/6,25 mg:

Active ingredient: Each film-coated tablet contains 5 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

BISOPROLOL CO UNICORN 10/6,25 mg:

Active ingredient: Each film-coated tablet contains 10 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

Inactive ingredients:

Colloidal silicon dioxide, corn starch, crospovidone, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and pregelatinised starch. The following colourants are also included: iron oxide red (5/6,25 tablets only) and opadry white.

What BISOPROLOL CO UNICORN looks like and contents of the pack

BISOPROLOL CO UNICORN 5/6,25: Pink-coloured, film-coated, round tablets debossed with “5” on one side and plain on the other side.

BISOPROLOL CO UNICORN 10/6,25: White to off-white-coloured, film-coated, round tablets debossed with “10” on one side and plain on the other side.

Clear PVC/PVDC/Aluminium foil blisters containing 10 tablets each. Three blister strips with a package insert are placed in an outer carton.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd.

Corner Searle & Pontac Streets,

Woodstock,

Cape Town,

8001

South Africa

This leaflet was last revised in

September 2021

Registration Number:

BISOPROLOL CO UNICORN 5/6,25: 46/7.1.3/0387

BISOPROLOL CO UNICORN 10/6,25: 46/7.1.3/0388

Applicant/HCR	Unicorn Pharmaceuticals (Pty) Ltd
Product name, strength & dosage form	BISOPROLOL CO UNICORN 5/6,25 Tablets BISOPROLOL CO UNICORN 10/6,25 Tablets
Date of submission	July 2023

Proposed Patient Information Leaflet for

BISOPROLOL CO UNICORN 5/6,25 Tablets

BISOPROLOL CO UNICORN 10/6,25 Tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BISOPROLOL CO UNICORN 5/6,25 TABLETS

BISOPROLOL CO UNICORN 10/6,25 TABLETS

Bisoprolol fumarate and hydrochlorothiazide

Sugar free.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
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- You suffer from uncontrolled heart failure or if you are receiving therapy for a weak heart.
- You have problems with a very slow heart beat or a heart block.
- You have cardiogenic shock which is a heart condition causing low blood pressure and circulatory failure.
- You have very low blood pressure.
- You suffer from asthma or from another disease causing severe breathing difficulties.
- You suffer from metabolic acidosis, a condition in which the blood is too acidic.
- You suffer from a condition marked by excessive production of thyroid hormones.

- You suffer from severe blood circulation problems in your limbs (such as Raynaud's syndrome which may cause your fingers and toes to tingle or turn pale or blue).
- You suffer from untreated phaeochromocytoma, which is a tumour of the adrenal gland.
- You have Addison's disease (your adrenal glands do not produce enough of their hormones).
- You are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**).
- You suffer from severe kidney or liver problems.
- You have porphyria (a disorder that affects how your body makes red blood cells).

Warnings and precautions

Take special care with BISOPROLOL CO UNICORN:

- If you are taking quinidine, as the combination of **BISOPROLOL CO UNICORN** with quinidine may cause life-threatening abnormal heart rhythms.
- If you suffer from any breathing difficulties.
- If you suffer from diabetes and are taking anti-diabetic medicines, such as insulin, you should regularly check your blood for low blood glucose levels. Signs of low blood sugar, such as fast heartbeat, may be masked by **BISOPROLOL CO UNICORN**.
- If you are taking certain medicines to treat irregular heartbeat, angina pectoris (chest pain on exertion) or to treat high blood pressure (e.g. disopyramide, clonidine, myocardial depressants or calcium antagonists, such as verapamil).
- If you experience sudden onset of chest pain, or if you already suffer from a mild form of angina.

- If you have been prescribed **BISOPROLOL CO UNICORN** and suffer from phaeochromocytoma (a tumour of the adrenal gland); this condition should be treated first, prior to taking **BISOPROLOL CO UNICORN**.
- If you suffer from psoriasis (marked by severe skin rashes).
- If you are due to have an operation. Tell the anaesthetist or the medical staff you are taking **BISOPROLOL CO UNICORN** tablets at least 48 hours before the operation.
- If you are wearing contact lenses, as **BISOPROLOL CO UNICORN** may decrease tear flow, causing eye irritation.
- If you previously experienced an allergic reaction to penicillin, or other medicines containing sulphonamides. **BISOPROLOL CO UNICORN** can cause eye problems that, if left untreated, may lead to vision loss; especially in patients with a history of allergy to penicillin and sulphonamides. Symptoms of eye problems can happen within hours to weeks of starting treatment.

Tell your doctor immediately if you have:

- Decrease in vision.
- Eye pain.
- If you have a history of allergies, since **BISOPROLOL CO UNICORN** may make it more likely that you develop an allergic reaction, or that such a reaction is more severe.
- If you suffer from kidney or liver problems.
- If you have high calcium levels in your body.
- If you have had gout.

- If you want to stop taking **BISOPROLOL CO UNICORN**. You must discuss this with your doctor first. You should stop taking **BISOPROLOL CO UNICORN** gradually and limit your amount of exercise during this period. Your doctor will guide you.
- If you previously had skin cancer or if you develop an unexpected skin lesion during treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays
  while taking **BISOPROLOL CO UNICORN**.

DO NOT give **BISOPROLOL CO UNICORN** to children younger than 12 years as safety and efficacy have not been established.

Other medicines and BISOPROLOL CO UNICORN

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

- You may experience extremely low blood sugar levels when taking **BISOPROLOL CO UNICORN** with oral blood sugar lowering medication or insulin.
- You may have impaired myocardial function (problems of the heart muscle or a heart block) when taking antidysrhythmic medicines used to treat an irregular or rapid heartbeat (such as lidocaine, quinidine, disopyramide, flecainide and propafenone), calcium channel blockers (such as verapamil or diltiazem) or phenothiazines (used for mental illness).
- You may experience a worsening of heart failure if you take **BISOPROLOL CO UNICORN** with other medicines to treat high blood pressure, such as methyldopa.

- Medicines in the beta-adrenoceptor agonist class (such as dopamine, dobutamine and isoprenaline) may alter the effects of **BISOPROLOL CO UNICORN**.
- Nasal decongestants (to open a blocked nose) used for colds, such as phenylephrine, pseudoephedrine or phenylpropanolamine, may increase your blood pressure.
- Using reserpine with **BISOPROLOL CO UNICORN** may cause life-threatening vasoconstriction (constricting of the blood vessels causing an increase in blood pressure).
- Digoxin (used to improve the strength and efficiency of the heart or control the rate and rhythm of the heart) may be used with **BISOPROLOL CO UNICORN**. Your doctor should monitor your pulse rate and response regularly.
- When **BISOPROLOL CO UNICORN** is used for a prolonged time with medication such as corticosteroids, you may have an increased risk of developing low blood potassium levels. If your blood potassium levels are low, you may develop weakness, confusion and mental depression. You need to inform your doctor immediately if you experience such symptoms.
- Anti-inflammatory medication (NSAID painkillers, such as indomethacin) may reduce the blood pressure lowering effects of **BISOPROLOL CO UNICORN** and may cause sodium and water retention with possible swelling of your feet, ankles, hands and/or face.
- Low salt content in the body may occur in patients taking trimethoprim (an antibiotic) or carbamazepine (for nervous system related conditions) with **BISOPROLOL CO UNICORN**.

BISOPROLOL CO UNICORN with food and drink:

The tablets can be taken with or without food.

BISOPROLOL CO UNICORN taken together with alcohol may cause dizziness or light-headedness.

Pregnancy and Breastfeeding and Fertility:

DO NOT take **BISOPROLOL CO UNICORN** if you are pregnant, plan to become pregnant, or suspect that you are pregnant. Contact you doctor or healthcare professional immediately.

DO NOT take **BISOPROLOL CO UNICORN** during breastfeeding.

Administration of **BISOPROLOL CO UNICORN** to pregnant mothers shortly before giving birth or during labour may result in the baby being born with low blood sugar, low muscle tone and/or a slow heartbeat.

Driving and using machines:

BISOPROLOL CO UNICORN may make you feel drowsy or dizzy. Therefore, please make sure you know how **BISOPROLOL CO UNICORN** affects you before driving or using machinery.

3. HOW TO TAKE BISOPROLOL CO UNICORN:

Always take **BISOPROLOL CO UNICORN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

Therapy may be initiated with the lowest dose of bisoprolol/hydrochlorothiazide 2,5/6,25 mg, taking one tablet per day. Another formulation should be used. Subsequent dose adjustment may be carried out with **BISOPROLOL CO UNICORN** tablets up to the maximum

recommended dose of one 10/6,25 mg tablet once daily as appropriate. The tablets should be taken at about the same time each day.

If you have any questions about the proper dose of **BISOPROLOL CO UNICORN**, ask your doctor.

Treatment with **BISOPROLOL CO UNICORN** should not be stopped abruptly.

BISOPROLOL CO UNICORN should not be given to children less than 12 years old (see **Take special care with BISOPROLOL CO UNICORN**).

If you take more BISOPROLOL CO UNICORN than you should:

In the event of overdosage, consult your doctor or pharmacist; if neither is available, contact 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 forget to take BISOPROLOL CO UNICORN:

Take the missed dose 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.**

4. POSSIBLE SIDE-EFFECTS:

BISOPROLOL CO UNICORN may have side-effects. Not all side-effects reported for **BISOPROLOL CO UNICORN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effect while taking **BISOPROLOL CO UNICORN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking BISOPROLOL CO UNICORN and contact your doctor or healthcare professional immediately:

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

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to BISOPROLOL CO UNICORN. You may need urgent medical attention or hospitalisation. All of these are very serious side-effects, but are less frequently encountered.

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

- Chest pain.
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Difficulty breathing.
- Discoloration of the skin and numbness of the fingers or toes.
- Unusual bruising and nosebleeds, or bleeding in the mouth and gums.
- Yellowing of the skin and whites of the eyes, also called jaundice..
- Changes to your skin (new growths or lesions) as this could be a sign of skin cancer.

These are all serious side-effects. You may need urgent medical attention. Serious side-effects occur less frequently.

Side-effects that may occur more frequently include:

- Drowsiness, trouble in sleeping, unusual tiredness or weakness.
- Low amount of platelets in the blood, or reduced amount of salt in the body.
- Decreased sexual ability.

Less frequent side-effects that may occur include the following:

- Blood cell disorders.
- Increase or decrease of sugar in the blood, or sugar in the urine.
- Gout (an increase of uric acid in the body).
- Inflammation of the pancreas or infection of the salivary glands.
- Inflammation of the lining of the mouth.
- Loss of appetite (anorexia), increase in weight.
- Anxiety and/or nervousness.
- Nightmares and vivid dreams, depression.
- Hallucinations (hearing or seeing things that are not there).
- Dizziness, headache, restlessness.
- Extreme tiredness.
- Tingling or numbness of limbs.
- Feeling dizzy when standing, fever.
- Dry, sore eyes, reduced tear flow.
- Blurred vision or seeing objects more yellow than they are.
- Temporary loss of hearing.
- Blocked nose.
- Nausea, vomiting, diarrhoea, abdominal pain, constipation.
- Skin rash, sensitivity of skin to the sun, sweating, loss of hair.

- Back pain or joint pain, muscle cramps or muscle weakness.
- Kidney problems.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 CO UNICORN**.

Adverse reactions must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za

5. How to store BISOPROLOL CO UNICORN:

- Store at or below 25 °C.
- Keep the blisters 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

BISOPROLOL CO UNICORN 5/6,25 mg:

Active ingredient: Each film-coated tablet contains 5 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

BISOPROLOL CO UNICORN 10/6,25 mg:

Active ingredient: Each film-coated tablet contains 10 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide.

Inactive ingredients:

Colloidal silicon dioxide, corn starch, crospovidone, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and pregelatinised starch. The following colourants are also included: iron oxide red (5/6,25 tablets only) and opadry white.

What BISOPROLOL CO UNICORN looks like and contents of the pack

BISOPROLOL CO UNICORN 5/6,25: Pink-coloured, film-coated, round tablets debossed with “5” on one side and plain on the other side.

BISOPROLOL CO UNICORN 10/6,25: White to off-white-coloured, film-coated, round tablets debossed with “10” on one side and plain on the other side.

Clear PVC/PVDC/Aluminium foil blisters containing 10 tablets each. Three blister strips with a package insert are placed in an outer carton.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd.

Corner Searle & Pontac Streets,

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8001

South Africa

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BISOPROLOL CO UNICORN 10/6,25: 46/7.1.3/0388