PATIENT INFORMATION LEAFLET FOR

CARVEDILOL UNICORN

SCHEDULING STATUS:

S3

Each **CARVEDILOL UNICORN 6,25 mg** tablet contains 6,25 mg carvedilol.

Each **CARVEDILOL UNICORN 12,5 mg** tablet contains 12,50 mg carvedilol.

Each **CARVEDILOL UNICORN 25 mg** tablet contains 25,00 mg carvedilol.

CARVEDILOL UNICORN 6,25 mg tablets contains sugar (lactose monohydrate 72,25 mg and sucrose 5,00 mg.

CARVEDILOL UNICORN 12,5 mg tablets contains sugar (lactose monohydrate 144,50 mg and sucrose 10,00 mg.

CARVEDILOL UNICORN 25 mg tablets contains sugar (lactose monohydrate 85,00 mg and sucrose 60,00 mg.

Read all of this leaflet carefully before you start taking CARVEDILOL 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.

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

1. CARVEDILOL UNICORN is used to treat:

- High blood pressure (hypertension). High blood pressure may lead to various forms of cardiovascular diseases.
- The doctor has prescribed **CARVEDILOL UNICORN** to you with a view to prolonging your life and reducing the risk of heart attack and stroke. If so directed by your doctor, you may take **CARVEDILOL UNICORN** together with another medicine with a blood pressure lowering effect.
- It is also used to reduce worsening congestive heart failure.
- Prevention of chest pains (angina pectoris). Even when you are on medication, you should continue with your diet and exercise, as directed by your doctor.

2. What you need to know before you take CARVEDILOL UNICORN

Do not take CARVEDILOL UNICORN:

- if you are hypersensitive (allergic) to carvedilol or any of the other ingredients of **CARVEDILOL UNICORN** (see **WHAT CARVEDILOL UNICORN CONTAINS**).
- if you have any chronic disease or metabolic disorder.

  Chronic diseases include heart disease, vascular disease, psoriasis or high thyroid activity.
- if you have low blood pressure, or metabolic acidosis. In these cases, your doctor will give you additional instructions.

- if you suffer from bronchial asthma, chronic obstructive pulmonary disease, severe liver insufficiency, slow heart rate or some other heart rhythm disorders, severe or unstable heart failure, pulmonary hypertension, pulmonale or cardiogenic shock.

Children: Safety has not been established.

Warnings and precautions:

Take special care with CARVEDILOL UNICORN:

- at the beginning of treatment and/or when dosage is increased be careful when rising. You may experience dizziness or vertigo. You should be especially careful if you have heart failure, or if you are using any other medicines with a blood pressure lowering effect.
- before major anaesthesia, surgery or allergic testing, inform the doctor that you are taking **CARVEDILOL UNICORN.**
- if you are being treated for phaeochromocytoma (tumour of an adrenal gland).
- if you are currently using clonidine (used to treat migraine or menopause flushes). Stopping the use of your clonidine medication whilst being treated with **CARVEDILOL UNICORN** may lead to a drastic increase of blood-pressure.
- if you had an acute heart attack which caused a dysfunction of the left ventricle of the heart.
- if you are experiencing an extremely low heart beat (less than 55 beats per minute) after initiating the use of **CARVEDILOL UNICORN**.
- if you should not discontinue your treatment with **CARVEDILOL UNICORN** abruptly if you have a known reduced blood supply to the heart.
- if you are suffering from a kidney disease and worsening of renal function occur, you should inform your doctor immediately.
- if you are suffering from diabetes. You should be aware that the use of **CARVEDILOL**

UNICORN may cause lowering of your blood sugar levels. Monitor your blood glucose regularly and adjust your diabetic treatment accordingly.

- if you are suffering from a chronic obstructive lung disease.
- if you have thyroid problems.
- if there is any discoloration of fingers and/or toes as a result of recent exposure to changes in temperature (cold or hot) or emotional events.
- if you suffer from poor blood circulation.
- if you are wearing contact lenses. You should be aware that **CARVEDILOL UNICORN** may reduce the formation of tears and cause dry eyes.
- if you have a history of chest pain due to coronary artery spasm, as **CARVEDILOL UNICORN** should be taken with caution if you are suffering from this condition.
- if you develop psoriasis which is associated with the use of beta-blockers (blood pressure lowering medicines).
- if you are taking any of the following medication: verapamil or diltiazem or other anti-dysrhythmic medicines (medicine controlling irregular heart beat).
- if your condition deteriorates, consult your doctor as soon as possible.

Other medicines and CARVEDILOL UNICORN

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

Please discuss the use of the following medicines or substances in combination with CARVEDILOL UNICORN with your doctor or pharmacist:

- Taking additional blood pressure tablets or tablets to reduce water content in the body (water tablets) may result in low blood pressure.
- Digoxin (used to treat heart failure or irregular heart beat) may lead to lowering of your blood pressure.

- Cimetidine (indicated for stomach ulcers, reduction of acid in the stomach and gastric reflux) can increase the amount of CARVEDILOL UNICORN in your body.
- The use of rifampicin (which is used in the treatment of tuberculosis) might result in a possible increase of your blood pressure.
- The effect of your insulin or other oral diabetic medicines may cause your blood sugar level to decrease. You should monitor your blood glucose levels regularly.
- Hydralazine (used for the treatment of high blood pressure) and alcohol may lead to a reduction in blood pressure.
- Concurrent use of other blood pressure treatment medication such as diltiazem may lead to very low blood pressure and a severe slow heart rate.
- Any other medicine used to treat high blood pressure (e.g. reserpine, quanethidine or bethanidine) as they might lead to very low blood pressure and heartbeat.
- Isoprenaline (used for slow heart rate, asthma or heart block) which could lead to diminished carvedilol effects.
- Quinidine, disopyramide, lignocaine, procainamide and phenytoin used for heart dysfunction.
- Using stimulating medication (adrenaline or noradrenaline) for slow heart rate or heart block, or to reduce blood flow to the extremities of your body, might reverse the action of CARVEDILOL UNICORN.
- You may find your blood pressure dropping more than usual with the concurrent use of antihistamines (containing phenothiazine).
- Simultaneous use of CARVEDILOL UNICORN with your immunosuppressant medication ciclosporin, may result in an increase of ciclosporin concentration in your body and needs to be monitored regularly.
- You should not take CARVEDILOL UNICORN whilst on treatment with medicines used for disturbed heart function, e.g. verapamil.
- Treatment with your clonidine (used for migraine or menopausal flush)

- Concomitant use of CARVEDILOL UNICORN and medicines that increase blood flow to the heart may decrease your blood pressure more than what is expected.

CARVEDILOL UNICORN with food and drink:

The tablet should be taken with a glass of water and together with a meal.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **CARVEDILOL UNICORN**.

Pregnancy: Safety has not been established and **CARVEDILOL UNICORN** should not be used in pregnant women.

Breastfeeding: Breastfeeding is not recommended during treatment with **CARVEDILOL** UNICORN, as carvedilol is excreted into breast milk.

Driving and using machinery:

You should avoid driving, operating machinery or performing potentially dangerous tasks if you experience dizziness, vision abnormalities, headaches, fatigue or related symptoms. These may lead to an accident.

CARVEDILOL UNICORN contains sugar (lactose monohydrate and sucrose). Patients with the rare hereditary conditions of lactose intolerance should not take CARVEDILOL UNICORN. If you have been told by your doctor that you have a intolerance to some sugars, contact your doctor before taking CARVEDILOL UNICORN.

3. HOW TO TAKE CARVEDILOL UNICORN:

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

Always take **CARVEDILOL UNICORN** exactly as your doctor has instructed you. You should

check with your doctor or pharmacist if you are unsure.

Take **CARVEDILOL UNICORN** after a meal with some water and preferably at the same time each day.

Your doctor will tell you how long your treatment with **CARVEDILOL UNICORN** will last. You must not change your dose or discontinue treatment without first consulting your doctor.

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

Hypertension:

The starting dose is 1 tablet of 12,5 mg one time a day (in the morning) or 1 tablet of 6,25 mg two times a day (in the morning and in the evening). The doctor may increase your dosage up to 1 tablet of 25 mg two times a day.

Your doctor will determine the duration of treatment.

Congestive Heart Failure:

The starting dose is 3,125 mg two times a day for at least 14 days. Thereafter the dosage will be increased in intervals of at least 14 days to 6,25 mg two times a day, then 12,5 mg two times a day and finally 25 mg two times a day. Conventional treatment with digitalis, diuretics or an ACE-inhibitor will be continued. The doctor will only increase the dose if you are responding positively to the treatment.

Angina Pectoris:

The starting dose is 12,5 mg two times a day and then increased after two days to 25 mg two times a day.

Persons with left ventricular dysfunction otherwise uncomplicated myocardial infection:

Your doctor will determine the correct dose for you and will closely monitor you during your treatment with **CARVEDILOL UNICORN.**

If you take more CARVEDILOL 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.

Mild overdosage may result in low blood pressure (with dizziness or vertigo; fainting is also possible) and slow heartbeat. It is usually sufficient to decrease the dose or even temporarily discontinue the medication.

Massive overdosage may seriously affect circulation, breathing, heart function and consciousness. The doctor will take the appropriate measures to treat the signs and symptoms of overdosage.

While waiting for medical assistance and if you are awake, make yourself vomit to empty the stomach. Place yourself in a lying position with the head lowered and feet slightly raised. In unconscious patients, lay the patient on the side and do not try and make them vomit.

If you forget to take a dose of CARVEDILOL UNICORN:

If you forget to take your medicine, take your recommended dose as soon as you remember. However, if it is time for your next scheduled dose, do not take the missing dose but instead resume your usual dosing schedule that has been established.

Do not take a 'double dose' to make up for missed doses.

Effects when treatment with CARVEDILOL UNICORN is stopped:

Do not discontinue treatment suddenly as this could cause adverse effects to your heart. Instead the dosage should be gradually reduced over 7 to 14 days.

You should be taking your medicines regularly as prescribed by your doctor.

If treatment with **CARVEDILOL UNICORN** has been stopped for longer than 14 days, the

treatment should be started from the lowest dose.

4. POSSIBLE SIDE EFFECTS:

CARVEDILOL UNICORN can have side effects.

The side effects during treatment are mostly mild and short-term and as a rule do not require discontinuation of treatment. Severe side effects requiring dose reduction or discontinuation of treatment occur very rarely.

Not all side effects reported for CARVEDILOL UNICORN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARVEDILOL UNICORN, please consult with your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **CARVEDILOL UNICORN** 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
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CARVEDILOL UNICORN.** 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:

- chest pain

- changes in the way your heart beats, for example, if you notice it beating very slow or irregularly
- difficulty breathing
- excessive urination
- visual disturbances

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

Tell your doctor if you notice any of the following:

- unusual bleeding or bruises, increased blood sugar or cholesterol levels, signs of infection such as fevers/chills or sore throat (you may have less white blood cells than is normal)
- rapid weight gain
- fatigue, headache, mental problems, sleep disturbances, cold hands or feet
- pain in the muscles or joints
- vision abnormalities, dry or sore eyes (could trouble you if you wear contact lens)
- severe blood pressure drop, causing you to experience dizziness or vertigo (the feeling of moving or spinning while you aren't moving), especially when getting up, syncope, chest pain
- swelling of feet or legs due to fluid build-up, pain in your legs, ankles, feet, arms and hands
- flu-like symptoms, stuffy nose, wheezing, asthma
- gastro-intestinal disturbances such as loss of appetite, diarrhoea, nausea or vomiting, abdominal pain, constipation, dry mouth
- rash, redness and itchiness of skin
- loss of bladder control
- sexual dysfunction

- nightmares
- muscle weakness
- gangrene.

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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of CARVEDILOL UNICORN.

6. Contents of the pack and other information

- Do not use **CARVEDILOL UNICORN** tablets after the expiry date stated on the carton.
- Store your tablets at or below 30 °C in a cool, dry place.
- Do not remove the blisters from outer carton until required for use.
- Do not put them into another container as they might get mixed up.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewage systems (e.g. toilets).

What CARVEDILOL UNICORN looks like and contents of the pack

CARVEDILOL UNICORN 6,25 mg, 12,5 mg and 25 mg are available in OPA/AL/PVC and

Aluminium foil blister packs of 30 tablets.

CARVEDILOL UNICORN 6,25 mg:

A white, oval, slightly biconvex tablet, one side scored with sign S2 on the opposite side.

CARVEDILOL UNICORN 12,5 mg:

A white, oval, slightly biconvex tablet, one side scored with sign S3 on the opposite side.

CARVEDILOL UNICORN 25 mg:

A white, round, slightly biconvex tablets, bevel-edged, one side scored.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Street

Cape Town

8001

South Africa

Application number(s)

CARVEDILOL UNICORN 6,25 mg: 37/7.1.3/0279

CARVEDILOL UNICORN 12,5 mg: 37/7.1.3/0280

CARVEDILOL UNICORN 25 mg: 37/7.1.3/0281

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