PATIENT INFORMATION LEAFLET

CARVETREND RANGE

SCHEDULING STATUS:

S3

CARVETREND 6,25 mg (tablets)

CARVETREND 12,5 mg (tablets)

CARVETREND 25 mg (tablets)

Carvedilol

CARVETREND contains sugar (lactose monohydrate and sucrose) in the following quantities per tablet, respectively:

CARVETREND 6,25 mg: (72,25 mg; 5,00 mg)

CARVETREND 12,5 mg: (144,50 mg; 10,00 mg)

CARVETREND 25 mg: (85,00 mg; 60,00 mg)

Read all of this leaflet carefully before you start taking CARVETREND

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

PATIENT INFORMATION LEAFLET

CARVETREND RANGE

1. What CARVETREND is and what it is used for

CARVETREND contains carvedilol. Carvedilol belongs to a group of medicines called beta blockers that work by relaxing and

widening the blood vessels. This makes it easier for your heart to pump blood around the body and reduces blood pressure and strain on your heart.

CARVETREND tablets are used to:

- treat high blood pressure (hypertension). High blood pressure may lead to various forms of cardiovascular diseases. The doctor has prescribed CARVETREND 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 CARVETREND together with another medicine with a blood pressure lowering effect.
- reduce worsening congestive heart failure.
- prevent 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 CARVETREND

Do not take CARVETREND:

- if you are hypersensitive (allergic) to carvedilol or any of the other ingredients of CARVETREND (listed in section 6)
- inform your doctor if you have any chronic disease, metabolic disorder, or if you are taking any other medication. Chronic diseases include heart disease, vascular disease, psoriasis or high thyroid activity
- tell the doctor if you have low blood pressure, any allergic reaction or metabolic acidosis. In these cases, your doctor will give you additional instructions
- CARVETREND tablets should not be taken 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, or cor pulmonale (pulmonary

heart disease) or cardiogenic shock

- if you suffer from a heart condition called variant or Prinzmetal angina, characterised by chest pain
- untreated phaeochromocytoma, a tumour that secretes chemicals like noradrenaline, causing symptoms like sweating, headache, rapid heartbeat and trembling
- if you suffer from a condition that occurs when the body produces excessive quantities of acid, also called metabolic acidosis. You may experience shallow breathing, confusion and tiredness
- if you suffer from severe disturbances in your blood vessels (arteries), where the blood vessels narrow and reduce blood flow to your limbs. You may experience numbness or tingling in your arms and legs
- if you are also taking calcium channel blockers (e.g. verapamil and diltiazem).

Warnings and precautions

Take special care with CARVETREND:

- at the beginning of treatment and/or when dosage is increased, be careful when rising (standing up), as your blood pressure may drop. You may experience dizziness or vertigo.
- you should be especially careful if you have heart failure, if you are using any other medicines with a blood pressure lowering effect.
- before surgery or allergic testing, inform the doctor that you are taking CARVETREND.

If your condition deteriorates, consult your doctor as soon as possible.

Inform your doctor or healthcare provider if:

- you are currently on digitalis therapy (taking digoxin)
- you are being treated for phaeochromocytoma (tumour of an adrenal gland)
- you are currently taking clonidine (a medicine used to treat migraine or menopause flushes). Stopping the use of your clonidine medication whilst being treated with CARVETREND may lead to a drastic increase of blood pressure
- you had an acute heart attack which caused a dysfunction of the left ventricle of the heart

- you are experiencing an extremely low heartbeat (less than 55 beats per minute) after initiating the use of CARVETREND
- you are currently taking cimetidine (a medicine used to treat heartburn)
- you should not discontinue your treatment with CARVETREND abruptly if you have a known reduced blood supply to the heart
- you are suffering from a kidney disease and worsening of kidney function occurs, you should inform your doctor immediately
- you are suffering from diabetes. You should be aware that the use of CARVETREND may cause lowering of your blood sugar levels. Monitor your blood glucose regularly and adjust your diabetic treatment accordingly
- you are suffering from a chronic obstructive lung disease, or allergic conditions that involve your airways
- you have thyroid problems
- there is any discolouration of fingers and/or toes as a result of exposure to changes in temperature (cold or hot) or emotional events
- you suffer from poor blood circulation
- you are wearing contact lenses. You should be aware that CARVETREND may reduce the formation of tears and cause dry eyes
- you are taking debrisoquine, a medicine used to lower your blood pressure
- you have a history of chest pain due to coronary artery spasm, as CARVETREND should be taken with caution if you are suffering from this condition
- you develop psoriasis which is associated with the use of beta blockers (blood pressure lowering medicines)
- you experience severe reactions like blistering of the skin, mouth, eyes and genitals
- you are taking any of the following medication: verapamil or diltiazem — especially via injection (see Do not take CARVETREND) or other antidysrhythmic medicines (medicine controlling irregular heartbeat).

Children and adolescents

Safety in children has not been established.

Other medicines and CARVETREND

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

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

- 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 heartbeat) 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 CARVETREND in your body.
- a group of medicines called phenothiazines (used in the treatment of psychiatric conditions, e.g. chlorpromazine, fluphenazine), as taking these medicines with CARVETREND can lower your blood pressure.
- simultaneous use of CARVETREND with your immunosuppressant medication ciclosporin may result in an increase of ciclosporin concentration in your body and needs to be monitored regularly.
- rifampicin (which is used in the treatment of tuberculosis) might result in a possible increase of your blood pressure.
- the effectivity of CARVETREND will be monitored while taking amiodarone (a medicine used to treat irregular heartbeat) with CARVETREND.
- levels of CARVETREND in your blood will be monitored by your doctor while you are taking medicines called barbiturates (used to treat seizures), ketoconazole (used to treat fungal infections), fluoxetine or paroxetine (used to treat depression), haloperidol (used to treat psychiatric disorders) and erythromycin (an antibiotic used to treat various infections), as these medicines may either enhance or reduce the effects of CARVETREND.

- 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.
- treatment with clonidine (used for migraine or menopausal flush) (see Take special care with CARVETREND).
- concurrent use of other blood pressure treatment medication, such as diltiazem and verapamil, 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, guanethidine, methyldopa or bethanidine), or monoamine oxidase inhibitors (MAOIs) (used in the treatment of depression, panic or social disorder), as they might lead to very low blood pressure and heartbeat.
- if you are going for major anaesthesia or surgery, you must tell your doctor that you are being treated with CARVETREND (see Take special care with CARVETREND).
- taking anti-inflammatory medicines with CARVETREND may increase blood pressure.
- isoprenaline (used for slow heart rate, asthma or heart block), which could lead to diminished effects of CARVETREND.
- hydralazine (used for the treatment of high blood pressure) and alcohol may lead to a reduction in blood pressure.
- 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 your blood pressure medication.
- you may find your blood pressure dropping more than usual with the concurrent use of antihistamines (containing phenothiazines).
- a group of medicines called nitrates (used to treat angina, e.g. nitroglycerine), as these may lower your blood pressure.
- the blood pressure lowering effect of CARVETREND may be reduced when taking oestrogen-containing contraceptives or corticosteroids (medicines used to treat inflammation).
- ergotamine (a medicine used in the treatment of migraines).

- Medicines used to decrease the heart rate should best not be used concurrently with CARVETREND.
- taking CARVETREND with medicines that increase blood flow to the heart may decrease your blood pressure more than expected.
- you must inform your doctor if you are currently using medicine to stimulate and restore your heartbeat. It may result in severe low heart rate.

CARVETREND with food and drink

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy: Safety has not been established and CARVETREND should not be used in pregnant women, as foetal harm may occur.

Breastfeeding: As carvedilol is excreted into breast milk, it should not be administered when breastfeeding.

Fertility: There is no data on fertility with CARVETREND.

Driving and using machines

CARVETREND has minor influence on the ability to drive and use machines.
CARVETREND may cause dizziness, vision problems, headaches, fatigue and reduced alertness, especially at the start of therapy and during dose adjustment.

It is not always possible to predict to what extent CARVETREND may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CARVETREND affects them.

CARVETREND contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CARVETREND.

3. How to take CARVETREND

Do not share medicines prescribed for you with any other person.
Always take CARVETREND exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment will last. You must not change your doses or discontinue treatment without first consulting your doctor. Take CARVETREND after a meal with some water and preferably at the same time each day.

Adults:

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.

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

angiotensin-converting enzyme (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 dysfunction:

- Your doctor will determine the correct dose for you and will closely monitor you during your treatment with CARVETREND.

Your doctor will tell you how long your treatment with CARVETREND will last. Do not stop treatment early because this could cause adverse effects to your heart.
If you have the impression that the effect of CARVETREND is too strong or too weak, tell your doctor or pharmacist.

If you take more CARVETREND 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.

Symptoms of overdose may include:

- 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.

If you forget to take CARVETREND

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 missed dose but instead resume your usual dosing schedule that has been established. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CARVETREND

Do not discontinue treatment suddenly as this could cause adverse effects to your heart. Instead, the dosage should be gradually reduced over 7 - 14 days. You should be taking your medicines regularly as prescribed by your doctor.

If treatment with CARVETREND has been stopped for longer than 14 days, the treatment should be started from the lowest dose.

4. Possible side effects

CARVETREND can have side effects.

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

If any of the following happens, stop using CARVETREND 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CARVETREND. 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 the skin and eyes, also called jaundice
- severe drop in blood pressure
- very slow or irregular heartbeat (less than 55 beats per minute)
- excessive urination
- pains in the chest
- visual disturbances
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- a more severe form of rash, causing extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis).

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:

- pale skin, and feeling weak or breathless
- rapid weight gain
- gastrointestinal disturbances such as loss of appetite, runny stomach, nausea and vomiting, upset stomach
- low blood pressure with vertigo or dizziness (particularly when rising)
- high blood pressure
- swelling
- lung and airway infections
- slow heartbeat

- fatigue
- headache
- pain in the muscles or joints
- increased blood sugar or cholesterol levels, struggling to control blood sugar levels if you are diabetic
- trouble seeing and irritation of your eyes
- feeling sad for long periods of time
- difficulty breathing, with wheezing
- cold hands or feet
- numbness and pain in legs and feet
- general pain.

Less frequent side effects:

- unusual bleeding or bruises
- chest pain or discomfort
- not passing stools regularly
- abnormal liver function test results
- hypersensitivity (allergic) reactions
- feeling of pins and needles
- feeling confused
- trouble controlling your bladder, especially if you are a woman
- the inability to get and keep an erection
- flu symptoms
- skin reactions like hives, itchiness and rash, increased sweating
- dry mouth and dry eyes (could trouble you if you are a contact lens wearer)
- hair loss.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of CARVETREND. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store CARVETREND

Store all medicines out of reach of children.

Store at or below 30 °C in a cool, dry place.

Keep blisters in the outer container until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARVETREND contains:

The active substance is carvedilol.

Each CARVETREND 6,25 mg tablet contains carvedilol 6,25 mg

Each CARVETREND 12,5 mg tablet contains carvedilol 12,5 mg

Each CARVETREND 25 mg tablet contains carvedilol 25 mg

The other ingredients are

Colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, povidone, sucrose.

What CARVETREND looks like and contents of the pack

CARVETREND 6,25 mg: A white, oval, slightly biconvex tablet, one side scored, with sign S2 on the opposite side.

CARVETREND 12,5 mg: A white, oval, slightly biconvex tablet, one side scored, with sign S3 on the opposite side.

CARVETREND 25 mg: A white, round, slightly biconvex tablet, bevel-edged, one side scored.

CARVETREND is available in OPA/Al/PVC and aluminium foil blister packs of 30 tablets.

Holder of Certificate of Registration

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CARVETREND 6,25 mg: A37/7.1.3/0276

CARVETREND 12,5 mg: A37/7.1.3/0277

CARVETREND 25 mg: A37/7.1.3/0278

NAMIBIA:

CARVETREND 6,25 mg: NS2 08/7.1.3/0105

CARVETREND 12.5 mg: NS2 08/7.1.3/0104

CARVETREND 25 mg: NS2 08/7.1.3/0103

BOTSWANA:

CARVETREND 6,25 mg: S2 BOT1101790

CARVETREND 12.5 mg: S2 BOT1101791

CARVETREND 25 mg: S2 BOT1101792

MOZAMBIQUE

CARVETREND 6,25 mg: 2851

CARVETREND 12.5 mg: 2853

CARVETREND 25 mg: C5667

ZAMBIA:

CARVETREND 6,25 mg: POM 051/014

CARVETREND 12.5 mg: POM 051/015