

PATIENT INFORMATION LEAFLET
CARVETREND RANGE

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

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, 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

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2. What you need to know before you use CARVETREND
3. How to use CARVETREND
4. Possible side effects
5. How to store CARVETREND
6. Contents of the pack and other information

1. What CARVETREND is and what it is used for

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 to any of the ingredients of CARVETREND (see section 6)

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- 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's 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).

Children: Safety has not been established.

Warnings and precautions

Take special care with CARVETREND:

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- 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 professional 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 heart beat (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.

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- You are suffering from a chronic obstructive lung disease, or allergic conditions that involve your airways.
- You have thyroid problems.
- There is any discoloration 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.
- If 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 or other anti-dysrhythmic medicines (medicine controlling irregular heart beat).

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 heart beat) may lead to lowering of

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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 (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.

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- Any other medicine used to treat high blood pressure (e.g. reserpine, guanethidine or bethanidine) 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.

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- Taking CARVETREND with medicines that increase blood flow to the heart may decrease your blood pressure more than what is expected.
- You must inform your doctor if you are currently using medicine to stimulate and restore your heart beat. 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, please consult your doctor, pharmacist or other healthcare professional for advice before using CARVETREND.

Pregnancy: Safety has not been established and CARVETREND should not be used in pregnant women.

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

Driving and using machines:

CARVETREND may cause dizziness, vision problems, headaches and fatigue.

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

CARVETREND contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take CARVETREND. If you have been told by your doctor

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

CARVETREND contains lactose and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take CARVETREND

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

Always use CARVETREND exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Your doctor will determine the duration of treatment. 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 ACE-inhibitor will be continued. The doctor will only increase the dose if you are responding positively to the treatment.

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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 overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

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

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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 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 missing 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 to 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

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 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,

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which may cause difficulty in swallowing or breathing

- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice
- severe drop in blood pressure.

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:

- very slow or irregular heart beat (less than 55 beats per minute)
- excessive urination
- pains in the chest
- visual disturbances

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
- gastro-intestinal 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

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- 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

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- 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. 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 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 CARVETREND.

5. How to store CARVETREND

- Store all medicines out of reach of children.
- Store in a cool (at or below 30 °C) dry place.
- Do not put them into another container as they might get mixed up. 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

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What CARVETREND contains

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

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

Each CARVETREND 25 mg tablet contains 25 mg carvedilol.

The other ingredients are:

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