

**PATIENT INFORMATION LEAFLET
CARVETREND RANGE**

SCHEDULING STATUS:**S3****PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:****CARVETREND 6,25 mg** tablet.**CARVETREND 12,5 mg** tablet.**CARVETREND 25 mg** tablet.**Please read this leaflet carefully before you start taking CARVETREND tablets.**

- Keep this leaflet with your medicine. You may need to read it again.
- If you have further questions, or are not sure about anything, ask your doctor or your pharmacist.
- **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.

1. WHAT CARVETREND CONTAINS:

The **active substance** is carvedilol.

The **other ingredients** are colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate, povidone and sucrose.

CARVETREND contains lactose and sugar.

2. WHAT CARVETREND IS USED FOR:

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

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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.

3. BEFORE YOU TAKE CARVETREND:

Do not take CARVETREND:

- If you are hypersensitive (allergic) to carvedilol or any of the other ingredients of **CARVETREND** (see **WHAT CARVETREND CONTAINS**).
- 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.

Children: Safety has not been established.

Special care should be taken with CARVETREND:

- At the beginning of treatment and/or when dosage is increased be careful when rising, 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**.

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

Inform your doctor or healthcare professional if:

- You are being treated for phaeochromocytoma (tumor of an adrenal gland).
- You are currently using clonidine (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 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 renal function occur, 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.
- 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.
- 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).

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- You are taking any of the following medication: verapamil or diltiazem or other anti-dysrhythmic medicines (medicine controlling irregular heart beat).

Pregnancy and breast-feeding:

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

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

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

You should avoid driving, operating machinery or perform potentially dangerous tasks if you are:

- feeling dizzy
- having problems with your vision
- experiencing headaches and fatigue

Important information about some of the ingredients of CARVETREND:

CARVETREND contains lactose and sugar.

Persons who are either lactose or sugar intolerant should not take **CARVETREND**.

Taking other medicines with CARVETREND:

- Always tell your healthcare professional if you are taking any other medicines. This includes complementary or traditional medicines.
- Taking additional blood pressure tablets or tablets to reduce water content in the body (water tablets) may result in low blood pressure.

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- 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 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.

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

- 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.
- 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 your blood pressure medication.
- You may find your blood pressure dropping more than usual with the concurrent use of antihistamines (containing phenothiazine).
- 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.
- You should not take **CARVETREND** whilst on treatment with medicines used for disturbed heart function, e.g. verapamil.

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- Medicines used to decrease the heart rate should best not be used concurrently with **CARVETREND**.
- If you are going for major anaesthesia or surgery, you must tell your doctor that you are being treated with **CARVETREND** (see BEFORE YOU TAKE **CARVETREND**).
- Treatment with your clonidine (used for migraine or menopausal flush) (see BEFORE YOU TAKE **CARVETREND**).
- Concomitant use of **CARVETREND** and 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.

4. HOW TO TAKE CARVETREND TABLETS:

- Do not share medicines prescribed for you with any other person.
- Always take **CARVETREND** exactly as your doctor has instructed you. 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.
- If you have the impression that the effect of **CARVETREND** 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.

Congestive Heart Failure:

- The starting dose is 3,125 mg two times a day for at least 14 days.

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- 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 dysfunction:

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

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.
- 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 CARVETREND:

- If you forget to take your medicine, take your recommended dose as soon as you remember.

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- 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 CARVETREND is suddenly 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 **CARVETREND** has been stopped for longer than 14 days, the treatment should be started from the lowest dose.

5. POSSIBLE SIDE EFFECTS:

CARVETREND 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 which require dose reduction or even discontinuation of treatment occur very rarely.

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 taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **CARVETREND** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, neck or face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- itching or rash
- fainting
- yellowing of the skin and eyes, also called jaundice

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- severe blood pressure drop

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:

- unusual bleeding or bruises
- rapid weight gain
- mood swings
- mental problems or sleep disturbances
- gastro-intestinal disturbances such as loss of appetite, diarrhoea, nausea and vomiting
- low blood pressure with vertigo or dizziness (particularly when rising)
- slow heartbeat
- fatigue
- sleepiness
- headache
- pain in the muscles or joints
- cold hands or feet
- dry mouth and dry eyes (could trouble you if you are a contact lens wearer)
- increased blood sugar or cholesterol levels
- urinary incontinence.

If you notice any side effects not mentioned in the leaflet, please inform your doctor or pharmacist.

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6. STORAGE AND DISPOSING OF CARVETREND

- Do not use **CARVETREND** tablets after the expiry date stated on the carton
- 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
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**