PATIENT INFORMATION LEAFLET

Information for the Patient about

CARLOC 6,25 / 12,5 / 25 (TABLETS)

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CARLOC 6,25 (Tablets)

CARLOC 12,5 (Tablets)

CARLOC 25 (Tablets)

Read all of this leaflet carefully before you start taking CARLOC:

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **CARLOC 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 CARLOC CONTAINS:

The active ingredient in **CARLOC** is carvedilol.

Each **CARLOC 6,25** tablet contains 6,25 mg of carvedilol.

Each **CARLOC 12,5** tablet contains 12,5 mg of carvedilol.

Each **CARLOC 25** tablet contains 25 mg of carvedilol.

Inactive ingredients are colloidal anhydrous silica, ferric oxide red, ferric oxide yellow, lactose monohydrate, low substituted hydroxyl propyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose and *purified talc.

* Only present in **CARLOC 25**.

Contains sugar (lactose).

WHAT CARLOC IS USED FOR:

CARLOC belongs to a group of medicines called beta-blockers. It is a vasodilator (medicine that opens (dilate) blood vessels). It works directly on the muscles in the walls of your arteries causing the arteries to relax and widen. This effect reduces your blood pressure and makes it easier for your heart to pump blood around your body. In combination with other medicines, **CARLOC** is used to treat weakening of the heart muscles (heart failure) and after a heart attack.

BEFORE YOU TAKE CARLOC:

Do NOT take CARLOC:

- If you are allergic (hypersensitive) to carvedilol or any of the inactive ingredients of **CARLOC**.
- If you have a history of wheezing due to asthma or chronic airway diseases.
- If you have allergic conditions involving the airways such as hay fever or swelling in the elongated space between the vocal cords (glottis oedema).
- If you are currently receiving a drip or injection of verapamil or diltiazem (used to treat high blood pressure or heart problems).
- If you have been diagnosed with a conduction defect of the heart called an AV second or third degree heart block or SA block.

- If you have been diagnosed with a very slow heartbeat.
- If you have been diagnosed with New York Heart Association (NYHA) Class IV heart failure (worsening of pumping action the heart) and require medicine in the form of a drip or injection.
- If you have been diagnosed with cardiogenic shock (a condition in which your heart suddenly cannot pump enough blood to meet your body's needs).
- If you have been diagnosed with sick sinus syndrome (also known as sinus node disease or sinus node dysfunction). It is the name for a group of heart rhythm problems (arrhythmias) in which the sinus node (the heart's natural pacemaker) does not work properly.
- If you have been diagnosed with liver disease.
- If you have been diagnosed with metabolic acidosis (a serious disorder where the body produces excessive quantities of acid or the kidneys are not removing enough acid from the body).
- If you have very low blood pressure.
- If you have been told by your doctor you have a condition called Prinzmetal's angina (cyclic chest pain).
- If you have been diagnosed with a tumour of the adrenal gland causing high blood pressure (phaeochromocytoma) and not receiving treatment.
- If you have very poor blood flow in the hands and feet causing coldness and pain in them (Raynaud’s phenomenon).
- If you are a child.

Take special care with CARLOC:

- When you are switching from clonidine to **CARLOC** as severe rebound high blood pressure may occur.
- If you have impaired renal function.
- If you suffer from phaeochromocytoma (a tumour of the adrenal gland causing high blood pressure). You should always take **CARLOC** in combination with a group of medicines called adrenoceptor blockers.
- If you suffer from any heart problems with a noticeable slow heart rate and you are receiving digoxin, diuretics (water tablets) or other high blood pressure tablets such as ACE inhibitors as treatment.
- If you are elderly or have a low basic blood pressure, salt and volume depletion or severe heart failure since low blood pressure may occur at the start or after an increase in the dose of your **CARLOC** treatment. Your doctor will monitor your response to treatment for approximately 2 hours after starting your **CARLOC** treatment or after increasing your dose. Your doctor will examine you for any symptoms of heart failure or dilation of blood vessels before increasing your **CARLOC** dosage.
- If you are using concurrent high blood pressure tablets such as diuretics (water tablets) or ACE inhibitors since your blood pressure can be significantly lowered. You should tell your doctor should you experience dizziness or feel faint. Your doctor may decide to reduce your dosage of these medicine should the low blood pressure persist.
- When you start **CARLOC** treatment or when your dosage is increased because temporary heart failure and water retention may occur. You should tell your doctor should you experience any shortness of breath or swelling. It may be necessary to lower your **CARLOC** dosage or discontinue therapy temporarily.

- If you are suffering from heart failure, low blood pressure, ischaemic heart disease (decreased oxygen in the heart usually due to decreased blood flow), generalised atherosclerosis (plaque build-up inside your arteries) or kidney disease since you may experience a reversible deterioration in your kidney function. Monitoring of your kidney function will be done with increases of your **CARLOC** dosage and your dosage might be reduced or the treatment stopped if required.
- If you are suffering from congestive heart failure and receiving digoxin, diuretics (water tablets) and/or ACE inhibitors because these medicines can slow down your heart impulse (A-V conduction).
- If you are suffering from asthma, bronchitis or any other chronic lung diseases because you may have trouble breathing. **CARLOC** should not be prescribed to you.
- If you have poor blood flow to your hands, feet or lower legs, or Raynaud's phenomenon because **CARLOC** can worsen your condition.
- If you are known to metabolise debrisoquine (high blood pressure medicine) poorly. You should be closely monitored during initiation of **CARLOC** therapy.
- If you are receiving concurrent treatment with medicines widening the blood vessels (alpha$_1$-receptor antagonist or alpha$_2$-receptor agonist) since limited knowledge on the behaviour of it exists.
- If you are suffering from the following medical conditions please tell your doctor:
    - Orthostasis (low blood pressure when standing)
    - Acute inflammatory heart disease (the inflammation of the heart causing fatigue, shortness of breath, fever, joint pain or swelling, achy feeling in the chest)

    - Labile or secondary hypertension (high blood pressure due to abnormalities in the blood vessels supplying blood to the kidneys)
    - Haemodynamic relevant obstruction of heart valves or outflow tract (a type of congenital heart defect in which either the right or left outflow chamber of the heart is blocked due to blood flow)
    - End-stage peripheral arterial disease (a critical narrowing of the arteries other than those that supply the heart or the brain)
- If you are scheduled to undergo an operation. Please inform your doctor or anaesthetist of your **CARLOC** therapy for them to manage your treatment appropriately.
- If you are discontinuing **CARLOC** treatment since the abrupt discontinuation of therapy may cause a worsening of angina pectoris. The discontinuation of **CARLOC** therapy should be gradual (over a period of 1 to 2 weeks). You should also limit the extent of your physical activity during the period that the medicine is being discontinued.
- If you have diabetes since **CARLOC** may hide your usual symptoms of low blood sugar. Regular blood sugar monitoring is recommended.
- If you are receiving concurrent calcium channel blocking medicines such as verapamil and diltiazem or other antidysrrhythmics (irregular heartbeat), specifically amiodarone. Your blood pressure and heart function should be monitored. You should never receive these medicines intravenously.
- If you are receiving concurrent treatment with cimetidine since the effect of **CARLOC** can be increased.
- If you have problems with your thyroid since **CARLOC** may hide your symptoms.

- If you wear contact lenses because **CARLOC** may cause the eyes to be drier than normal.
- If you have psoriasis (a skin condition characterised by red, itchy, scaly patches) because **CARLOC** can worsen the condition.
- If you have or have ever had a serious allergic reaction or you are undergoing allergic desensitisation therapy for any type of severe allergy.

Taking CARLOC with food and drink:

CARLOC should be swallowed with a full glass of water.

If you are taking **CARLOC** to treat heart failure, you should take it with water after you had a meal (see **"HOW TO TAKE CARLOC"**).

Taking **CARLOC** with alcohol may cause impairment of your ability to drive or operate machinery (see **"Driving and using machinery"**).

Pregnancy and breastfeeding:

Do not take **CARLOC** while you are pregnant or breastfeeding your baby. **CARLOC** is excreted in breast milk.

Consult your doctor immediately if you become pregnant while taking **CARLOC**.

Taking **CARLOC** shortly before giving birth, or during labour, may result in the new-born infant being born with low muscle tone, collapsed and low blood sugar. **CARLOC** may cause death, immature or premature delivery of your unborn child.

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

Driving and using machinery:

CARLOC may cause you to feel dizzy and light-headed and may therefore affect your ability to drive or operate machinery. Do not drive or operate machinery until you know how **CARLOC** affects you.

Do not drink alcohol whilst taking **CARLOC** as it may worsen the effects of alcohol.

Important information about some of the ingredients of CARLOC:

CARLOC contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **CARLOC.**

Taking other medicines with CARLOC:

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

Please inform your doctor if you are taking or will be receiving any of the following medicines:

- Medicines used to reduce blood pressure e.g. doxazosin, reserpine, amlodipine or indoramin.
- Medicines used to treat migraine e.g. clonidine or ergotamine.
- Medicines such as cyclopropane or trichloroethylene used as anaesthetics during an operation.

- Medicines used to treat abnormal heart rhythms e.g. diltiazem, disopyramide, procainamide, verapamil or amiodarone.
- Nitrate medicines for angina e.g. isosorbide mononitrate or glyceryl trinitrate since it the effect of **CARLOC** is increased.
- Painkillers such as non-steroidal anti-inflammatory medicines (NSAIDs) e.g. ibuprofen or diclofenac since it reduces the effect of **CARLOC**.
- Medicines to control your blood sugar level e.g. insulin or sulphonylureas.
- Medicines such as lidocaine (anaesthetic) or phenytoin (for epilepsy) as these medicines reduces the heartbeat.
- Medicines such as norepinephrine (noradrenaline), epinephrine (adrenaline) or isoprenaline used to stimulate heart function.
- Medicines such as quinidine that affects the metabolism of **CARLOC**.
- Medicines used to treat depression or other mental health conditions e.g. phenothiazines or monoamine oxide inhibitors.
- Medicines used to treat bacterial infections e.g. rifampicin or erythromycin.
- Medicines used to treat heart failure e.g. digoxin.
- Medicines used to treat stomach ulcers, heartburn and acid reflux e.g. cimetidine.

HOW TO TAKE CARLOC:

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

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

CARLOC should be swallowed with a full glass of water.

If you are taking **CARLOC** to treat heart failure, you should take it with water after you had a meal.

High blood pressure:

Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.

Adults:

The usual starting dose is:

12,5 mg once daily, initially, for two days. Thereafter 25 mg once daily.

If required, your doctor may increase the dose further.

Elderly:

The usual dose is 12,5 mg once daily.

If necessary your doctor may increase your dosage to 25 mg once daily or 12,5 mg twice daily at intervals of at least 2 weeks.

Heart failure (in conjunction with standard therapy):

*To reduce side-effect effects such as dizziness, light-headedness and feeling faint, take **CARLOC** with food to slow the rate of absorption.*

Adults:

The usual starting dose is 3,125 mg twice daily for two weeks. Your doctor will then increase your dosage to 6,25 mg twice daily for two weeks, and may then further increase the dose to 12,5 mg twice daily for another two weeks.

If you weigh less than 85 kg, the maximum recommended maintenance dose is 25 mg twice daily. If you weigh more than 85 kg, your doctor may increase your dosage to a maximum of 50 mg twice daily.

If you have stopped taking **CARLOC** for two weeks or more, you will need to return to the starting dose of 3,125 mg twice daily for two weeks and increase the dosage in line with the abovementioned dosage instructions.

Dysfunctional left lower chamber of the heart following otherwise an uncomplicated sudden heart attack.

In conjunction with your other treatment, your doctor will usually initiate treatment at 6,25 mg and carefully monitor your response before adjusting your dosage, as necessary.

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

If you take more CARLOC 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.

You may feel dizzy, sick, faint, breathless, wheezy, very drowsy, or experience convulsions.

If you forget to take CARLOC:

Always take **CARLOC** as prescribed. If you miss a dose, take it as soon as you remember, provided it is not nearly time for your next dose. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

CARLOC can have side-effects.

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

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

- Those that occur frequently:
    - Allergic reactions which may include a skin rash with blister formation (which may be life-threatening), or purple / red, inflamed spots on your skin.
    - Excessive hunger or thirst, frequent urination, blurred vision, fatigue, weakness, sweating, shaking or trembling, or if you feel faint or dizzy (especially if you have been diagnosed with diabetes mellitus), since this may be due to high or low blood sugar levels and may result in coma.
    - Heart failure (shortness of breath, difficulty breathing, generalised swelling and tiredness).

- Slow heartbeat.
- Generalised swelling (oedema).
- Kidney failure and abnormal functioning of the kidneys in patients with diffuse cardiovascular disease and/or renal insufficiency.

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

- Those that occur frequently:
  - Respiratory tract infection (coughing and fever).
  - Urinary tract infection (abnormal urination, burning sensation when urinating or discoloured urine).
  - Bruising of the skin, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever and chills, as these symptoms may be due to abnormal blood cell and platelet counts.
  - Dry eyes, blurred vision and eye irritation.
  - Swelling in the abdomen, hands, feet and ankles with difficulty breathing, shortness of breath and a rapid pulse.
  - Breathlessness.
  - Water accumulation in the lungs (difficulty breathing and coughing up blood).

    - Muscle weakness, wasting and cramps associated with pain and tenderness.
    - An abnormal heart rhythm, for example, if you notice it beating slowly.
- Those that occur less frequently:
    - Hypersensitivity (allergic reactions) skin rashes, hives or itching.
    - Psychotic reactions.
    - Seeing or hearing things that are not real.
    - Confusion.
    - Pins and needles.
    - Temporary loss of consciousness.
    - Eye pain.
    - Chest pain.
    - Angina.
    - Blood in the urine.

Tell your doctor if you notice any of the following:

- Those that occur frequently:
    - Weight increase.
    - Increased measured cholesterol value.
    - General feeling of discomfort, illness, or lack of well-being.
    - Depressed mood.
    - Dizziness and headache.
    - Low blood pressure, causing you to feel dizzy or light-headed especially upon standing up.
    - Numb and cold fingers and toes (extremities).

- Stomach cramps.
- Vomiting.
- Indigestion.
- Nausea and diarrhoea.
- Urinary disorders.
- Fatigue.
- Generalised pain.

- Those that occur less frequently:
  - Sleep disorders.
  - Vivid dreams and nightmares.
  - Stuffy or blocked nose.
  - Constipation and/or dry mouth.
  - Skin rash.
  - Reversible hair loss.
  - Involuntary leakage of urine in women.
  - Erectile dysfunction.
  - Fever.

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

STORING AND DISPOSING OF CARLOC:

Store in well closed containers, at or below 30 °C, protected from light.

Keep the blisters in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF CARLOC:

CARLOC 6,25: 30 or 60 tablets per pack in blister strips of 10 tablets.

CARLOC 12,5: 30 or 60 tablets per pack in blister strips of 10 tablets.

CARLOC 25: 30 or 60 tablets per pack in blister strips of 10 tablets.

IDENTIFICATION OF CARLOC:

CARLOC 6,25: Buff coloured, circular, biconvex tablets with cross break-line on one side and plain on the other.

CARLOC 12,5: Cream coloured, circular, biconvex tablets with cross break-line on one side and plain on the other.

CARLOC 25: Light red coloured, circular, biconvex tablets with cross break-line on one side and plain on the other.

REGISTRATION NUMBERS:

CARLOC 6,25: 37/7.1.3/0613

CARLOC 12,5: 34/7.1.3/0433

CARLOC 25: 34/7.1.3/0434

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

Cipla Medpro (Pty) Ltd.,

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