**PATIENT INFORMATION LEAFLET**

CARVEDILOL 6,25 OETHMAAN

Carvedilol 6,25 mg

Contains sugar (lactose monohydrate 72,25 mg and sucrose 5 mg)

CARVEDILOL 12,5 OETHMAAN

Carvedilol 12,5 mg

Contains sugar (lactose monohydrate 144,50 mg and sucrose 10 mg)

Read this entire leaflet carefully before you start taking/using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

CARVEDILOL 6,25 OETHMAAN tablets

CARVEDILOL 12,5 OETHMAAN tablets

WHAT CARVEDILOL OETHMAAN CONTAINS

Carvedilol Oethmaan 6,25 / 12,5 tablets contain carvedilol 6,25 mg or 12,5 mg per tablet as the active ingredient.

Inactive ingredients for all two strengths are: lactose, sucrose, crospovidone, povidone K25, silica colloidal anhydrous and magnesium stearate.

## WHAT IS CARVEDILOL OETHMAAN AND WHAT IS USED FOR

Carvedilol Oethmaan contains carvedilol which is a beta-blocker and dilates blood vessels (vasodilator).

It is used for the treatment of angina (chest pain) and mild to moderate heart failure.

Carvedilol Oethmaan is also used to treat high blood pressure.

## BEFORE YOU TAKE CARVEDILOL OETHMAAN

If you answer yes to any of the following questions please consult with your doctor before starting your treatment:

- Have you been told you suffer from any other heart problems?
- Have you had any problems with your liver, kidneys or thyroid?
- Do you have diabetes?
- Do you have a skin condition known as psoriasis?
- Do you have a circulation disorder (usually affecting the fingers) called Raynaud's phenomenon?
- Have you ever had a serious allergic reaction or are you undergoing allergic desensitisation therapy?
- Do you wear contact lenses?
- Do you suffer from a disease called Prinzmetal's angina?
- Do you suffer from Lapp lactase deficiency, fructose intolerance, glucose-galactose malabsorption or isomaltase insufficiency? This product contains lactose and should not be taken if you have any of these rare hereditary conditions.

Do not take this medicine if:

- you are allergic to carvedilol or to any other ingredients in this tablet.
- you have a history of wheezing due to asthma or other lung diseases.

- you have been told you have very severe heart failure and are breathless, even when sitting.
- you have a liver disease.
- you have low blood pressure.
- you have been told you have a very slow heartbeat.
- you have phaeochromocytoma (a tumour of the adrenal gland causing high blood pressure).
- you have a conduction defect of the heart (or heart block).
- you are pregnant or breastfeeding

If any of these apply to you, consult your doctor or pharmacist.

Before you have an operation:

Tell your hospital you are taking Carvedilol Oethmaan if you need to have an anaesthetic for surgery.

Children and Adolescents (under 18 years old): Carvedilol Oethmaan tablets are not recommended.

Using Carvedilol Oethmaan with food:

Take the tablets with a drink of water, without chewing or crushing them. You should try to take the tablets with food. You should take your tablets even if you do not have much appetite.

Pregnancy and breastfeeding:

If you are pregnant or breast-feeding DO NOT TAKE this medicine until you have talked to your doctor. Consult your doctor immediately if you become pregnant while taking this medicine.

Driving and using machines:

If you feel tired or dizzy while taking your tablets, you should not drive or operate machinery. Consumption of alcohol should be avoided, as these symptoms may be made worse.

Taking other medicines with Carvedilol Oethmaan:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Carvedilol Oethmaan with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice. Medicines that can cause possible interactions are:

- Other medicines that are used for lowering blood pressure.
- Anti-inflammatory medicines can decrease the effectiveness of your medicine.
- Other heart depressant medicines such as medicines that influence the rhythm of your heart beat.
- The effects of insulin and oral medicines for diabetes can be influenced by CARVEDILOL OETHMAAN.
- Concomitant administration of CARVEDILOL OETHMAAN with digoxin (a medicine against heart failure) may result in higher blood levels of digoxin. Digoxin levels should be monitored when CARVEDILOL OETHMAAN therapy is started, changed or stopped. Beta-blockers may potentiate slower heart beat caused by digoxin.
- Concomitant administration of cimetidine (a medicine that decrease acid secretion in the stomach) with CARVEDILOL OETHMAAN may alter the effects of your medicine.
- The effects of CARVEDILOL OETHMAAN may be reduced when given with rifampicin (an anti-TB medicine).
- Alcohol may lead to an increase in CARVEDILOL OETHMAAN effects as they are both metabolised by the liver.

Not all medicines that may cause interactions are listed here; please consult your doctor,

pharmacist or healthcare professional if you are uncertain.

HOW TO TAKE CARVEDILOL OETHMAAN:

Always take Carvedilol Oethmaan as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is:

Heart failure: Adults and elderly:

Carvedilol Oethmaan tablets should be taken twice a day - in the morning and in the evening. Starting with a very low dose, your doctor will gradually increase the strength of tablets you take until you receive the dose that suits you best.

High blood pressure: Adults:

The usual starting dose is 12,5 mg once each day for the first two days. After this, the dose is increased to 25 mg once each day. If necessary, your doctor may gradually increase the dose further at intervals of two weeks or more.

Elderly:

Your doctor will usually start you on 12,5 mg each day and continue with this dose for the length of your treatment. However, if necessary, your doctor may increase your dose gradually at intervals of two weeks or more.

If you take more Carvedilol Oethmaan than you should:

If you accidentally take too many tablets (overdose), you may feel dizzy, faint, breathless/wheezy, or extremely tired. Consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take Carvedilol Oethmaan:

- If you forget to take a dose take the dose as soon as you remember.
- If it is almost time for your next dose, ignore the dose you missed and take the next tablet at the normal time.
- Do not take a double dose to make up for the dose that you missed.
- If you have missed several doses, consult your doctor.

Effects when treatment with Carvedilol Oethmaan is stopped:

Do not suddenly stop taking Carvedilol Oethmaan tablets before you have spoken to your doctor about it. You may have side effects if you suddenly stop the tablets. Your doctor will tell you how to reduce and then stop this medicine. If you are also taking clonidine, never stop the treatment unless directed by your doctor.

POSSIBLE SIDE EFFECTS

Carvedilol Oethmaan can have side effects.

If any of the following happen, consult your doctor immediately, or go to the casualty department at your nearest hospital.

- If you get skin problems for the first time (such as rash or itching).
- Wheezing or difficulty breathing.

Very common side effects (affecting more than 1 in 10 people) include:

Headache, muscle pain, fatigue, dizziness (especially when standing up), a slowed heart beat (perhaps causing fainting and severe tiredness), stomach discomfort, diarrhoea, increased glucose and cholesterol levels in blood, disturbed vision and dry eyes.

Common side effects (affecting more than 1 in 100 people) include:

Breathlessness, asthma, nausea, abdominal pain, diarrhoea and an increase in cholesterol in the blood.

Rare side effects (affecting 1 to 10 people in every 10,000 people) include:

Tendency to bruise easily or have abnormal bleeding (for example, bleeding gums), reduced number of white blood cells, cold hands or feet, swelling of the feet or ankles, problems with sleeping, depression, fainting, nasal congestion, vomiting (being sick), constipation, changes in liver enzyme levels and skin reactions (including nettle rash, itching and aggravation of psoriasis).

Very rare side effects (affecting 1 to 10 people in every 10,000 people) include:

Visual disturbances, eye irritation, dry mouth; difficulty in passing water, failure of ejaculation

in men and angina or heart problems.

Many of the more common symptoms usually occur at the beginning of treatment and become less as treatment continues.

In patients with heart failure some of the side effects listed may occur more frequently and some less frequently than patients being treated for hypertension or angina.

If you suffer from any of these side effects, and they get worse or inconvenient, consult your doctor or pharmacist immediately. Do not stop taking these tablets until you have consulted with your doctor.

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

## STORING AND DISPOSING OF CARVEDILOL OETHMAAN

Store in the original packs below 25 °C. Protect from moisture and light.

Keep all medicines out of the reach and sight of children.

Do no use Carvedilol Oethmaan after the expiry/use before date on the label/carton.

Return all unused medicine to your pharmacist.

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

## PRESENTATION OF CARVEDILOL OETHMAAN

Carvedilol Oethmaan are packed into two types of containers:

- OPA/PVC aluminium blister packs of 28 or 30 tablets or
- white, plastic, round containers with child-resistant, tamper-proof screw closures containing 100 or 250 tablets.

## IDENTIFICATION OF CARVEDILOL OETHMAAN

Carvedilol Oethmaan 6,25 tablets are white, oval, slightly biconvex tablets, one side scored with S1 sign on the opposite side.

Carvedilol Oethmaan 12,5 tablets are white, oval, slightly biconvex tablets, one side scored with S2 sign on the opposite side.

REGISTRATION NUMBERS

CARVEDILOL 6,25 OETHMAAN: A39/7.1.3/0555

CARVEDILOL 12,5 OETHMAAN: A39/7.1.3/0556

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

Oethmaan Biosims (Pty) Ltd.

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