1.3.2 Patient Information Leaflet

Read the entire leaflet correctly before you start taking this medicine

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

Scheduling status:

S3

Name of medicines:

RUBITREND 6,25 (tablets)

RUBITREND 12,5 (tablets)

RUBITREND 25 (tablets)

What the medicine contains:

RUBITREND 6,25: Each tablet contains 6,25 mg Carvedilol

RUBITREND 12,5: Each tablet contains 12,5 mg Carvedilol

RUBITREND 25: Each tablet contains 25 mg Carvedilol

Other inactive ingredients:

Lactose, Crospovidone, Polyvinyl pyrrolidine, sucrose, magnesium stearate, colloidal silicon dioxide.

What this medicine is used for:

RUBITREND is indicated for the treatment of: -

- Chronic heart failure
- High blood pressure (hypertension)

Before taking this medicine:

Make sure it is safe for you to take this medicine

Do not use this product if:

- You are sensitive or ever had a harmful reaction to Carvedilol or any of the other inactives
- You have ever had wheezing due to asthma or other lung diseases
- You have problems with your liver
- You have problems with your heart e.g. slow heart beat. **RUBITREND** is not suitable for some heart conditions
- You have very low pressure
- You have a problem with acid levels in your blood (Metabolic acidosis)
- You have a growth on one of your adrenal glands
- You have problems with blood circulation in your fingers and toes (Raynaud's Phenomenon)
- You are pregnant or breast-feeding

Use with caution if:

- If you have problems with your kidneys
- You have high blood sugar (diabetes)
- You wear contact lenses
- You ever had problems with your thyroid
- You have a skin disorder called psoriasis after taking beta-blocker medicines

- You have a type of angina called "Prinzmetal's variant angina"

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take this medication.

Driving and using machinery:

You may feel dizzy while using **Gulf Carvedilol.** This is more likely when you start treatment or if your treatment is changed and when you drink alcohol. If this happens to you then do not drive or use any tools or machinery.

If you are pregnant or breast feeding your baby while taking this medicine consult your doctor, pharmacist or other health care professional for advice.

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

How to take the medicine:

RUBITREND may be taken with or without food preferably at the same time every day.

Hypertension:

Initial dose: 6.25 mg daily for 1 to 2 weeks or 12.5 mg daily for 2 days.

Maintenance dose: 12.5 mg twice daily or 25 mg once daily.

Elderly:

Usual dose is 12.5 mg daily. If necessary the dose can be increased to 25 mg once daily or divided doses after 2 weeks.

Heart failure:

Take the tablets at the same time as eating some food.

Initial dose: 3.125 mg twice daily for 2 weeks which can be increased to 6.25 mg daily for 2 weeks.

<85 kg the maintenance dose is maximum of 25 mg twice daily.

>85 kg the maintenance dose is maximum of 50 mg twice daily.

Your doctor will adjust your dose if necessary after every 2 weeks.

Do not share medicines prescribed for you with others.

If you take more RUBITREND than you should:

Treatment of overdose is symptomatic and supportive. Activated charcoal can be used for severe over-dose. The following effects may happen to you: a slow heart beat, feeling dizzy or light headed, becoming breathless, wheezy or extremely tired.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

Possible Side effects:

The following side effects can occur with use of this product:

The very common (> **1 in 10 people) side effects include:**

Feeling dizzy, headache (this is usually mild and occurs at the start of your treatment), feeling weak and tired.

The common (< **1 in 10 people) include:**

Increase in weight, increase in cholesterol, loss of control of blood sugar, slow heart beat, low blood pressure, fluid retention (signs include swollen fingers and ankles), nausea, diarrhoea, vomiting or problems with your sight.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Storage and disposal information:

Store at or below 25°C in a dry place. Do not remove tablets from unit carton until required for use.

Protect from light and moisture. Keep HDPE containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

Return all unused or expired medicines to your pharmacist.

Presentation:

Unit carton containing 28 (2 x 14) or 30 (3 x 10) tablets in clear PVC/silver Al blister packs.

White HDPE container and cap with 30, 100, 500 or 1000 tablets

Identification of the medicine:

RUBITREND 6,25 - Pale yellow to off white, round, flat tablet with central break-line

RUBITREND 12,5 - Pink coloured, circular flat tablets

RUBITREND 25 - White coloured, round, flat tablet with central break-line

Registration number:

RUBITREND 6,25: 43/7.1.3/0951

RUBITREND 12,5: 43/7.1.3/0952

RUBITREND 25: 43/7.1.3/0952

The Name and the Business Address of the Holder of the Certificate of Registration:

Gulf Drug Company (Pty) Ltd

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Mount Edgecombe, 4300

www.gulfdrug.co.za

Date of publication of the Patient Information Leaflet:

30 September 2016.