Please read this leaflet carefully before you start to take this medicine, even if you have just refilled the prescription or used this medicine before. The information in the previous leaflet may have changed. If you have further questions, please ask your doctor or your pharmacist. This medicine 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.

SCHEDULING STATUS:

S3

PROPRIETARY NAME (AND DOSAGE FORM):

Cardugen 1 mg (Tablets)

Cardugen 2 mg (Tablets)

Cardugen 4 mg (Tablets)

WHAT CARDUGEN TABLETS CONTAIN:

There are three strengths of Cardugen tablets available containing either 1 mg, 2 mg or 4 mg of the active ingredient doxazosin (as the doxazosin mesylate). Each tablet also contains sodium lauryl sulphate, lactose (anhydrous), microcrystalline cellulose, sodium starch glycollate and magnesium stearate.

WHAT CARDUGEN TABLETS ARE USED FOR:

Cardugen is used for the treatment of mild to moderate high blood pressure.

Cardugen is also used for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia.

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BEFORE TAKING CARDUGEN TABLETS:

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

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

Do not take this medicine and tell your doctor if:

- You have had an allergic or unusual reaction to doxazosin or any other quinazoline in the past.
- You are pregnant or plan to become pregnant.
- You are breast-feeding.

No experience is available on the use of Cardugen in children and it should therefore not be used in children.

HOW TO TAKE CARDUGEN TABLETS:

Hypertension:

The starting dose of Cardugen is 1 mg taken once a day.

Depending on the patient's response, the dosage may be increased after 1 – 2 weeks of treatment to 2 mg. Thereafter the dosage may be increased at similar intervals of 1 – 2 weeks to 4mg, 8 mg and 16 mg to achieve the desired reduction in blood pressure. Cardugen may also be given together with a thiazide agent to increase excretion of urine or a beta-blocking agent if the patient's blood pressure is not adequately controlled by Cardugen alone.

Benign Prostatic Hyperplasia:

The starting dose of Cardugen is 1 mg taken once a day.

Depending on the patients response, the dosage may be increased to 2 mg and thereafter to 4 mg and up to a maximum dose of 8 mg daily. The recommended time interval between increasing the dosage as required is 1 – 2 weeks.

The usual recommended dose is 2-4 mg once daily and blood pressure should be monitored regularly in these patients.

POSSIBLE SIDE-EFFECTS:

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 healthcare professional for advice.

The most common side-effects that are associated with Cardugen tablets are dizziness, headache, tiredness, low blood pressure, swelling due to retained fluid and lack of energy. Other side-effects include abnormal vision, chest pain, depression, frequent or loose watery stools, dry mouth, difficulty in breathing, inability to sleep,

queasiness, nervousness, rapid irregular action of the heart, rash, rhinitis, sexual dysfunction, sleepiness, increased rate of heart beat and a vague feeling of bodily discomfort.

Extremely rare cases of inability to control urinary function were reported.

Cases of persistent abnormal erection of the penis and inability of male function have also been reported.

The following effects have also been reported: severe pain in the chest, heart attack, stroke, irregular heart beat and blurred vision.

Less frequent cases of non-specific gastric complaints and cases of agitation and tremor have also been reported. Cases of allergic drug reactions have also been reported.

The ability to operate machinery or operate a motor vehicle may be impaired, especially when starting therapy.

If you should suffer from any of these unwanted side-effects or any effect not mentioned in this leaflet, tell your pharmacist or doctor.

STORING AND DISPOSING OF CARDUGEN TABLETS:

Store below 25 ºC. Protect from light. Keep original containers well closed. Do not remove the blisters from the carton until required for use.

Keep all medicines out of the reach of children.

PRESENTATION OF CARDUGEN TABLETS:

Cardugen 1 mg tablets are packed into blister strips and are placed into cardboard outer cartons of 30 tablets or, they are packaged into plastic securitainers of 30, 100 or 1000 tablets.

Cardugen 2 mg tablets are packed into blister strips and are placed into cardboard outer cartons of 30 tablets or, they are packaged into plastic securitainers of 30, 100 or 1000 tablets.

Cardugen 4 mg tablets are packed into blister strips and are placed into cardboard outer cartons of 30 tablets or, they are packaged into plastic securitainers of 30, 100 or 1000 tablets.

IDENTIFICATION OF CARDUGEN TABLETS:

Cardugen 1 mg tablets: White, round, biconvex tablets.

Cardugen 2 mg tablets: White, round, biconvex tablets.

Cardugen 4 mg tablets: White, round, biconvex tablets.

REGISTRATION NUMBER:

Cardugen 1 mg: 34/7.1/0271

Cardugen 2 mg: 34/7.1/0272

Cardugen 4 mg: 34/7.1/0273

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

Mylan (Pty) Ltd.

Greenstone Hill office Park

Building 6, Emerald Boulevard

Modderfontein

1645

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

To be allocated