



Composition

Each Cardular 1 mg tablet contains: 1.21 mg of Doxazosin Mesylate equivalent to 1 mg of doxazosin.
Each Cardular 2 mg tablet contains: 2.43 mg of Doxazosin Mesylate equivalent to 2 mg of doxazosin.
Each Cardular 4 mg tablet contains: 4.85 mg of Doxazosin Mesylate equivalent to 4 mg of doxazosin.
Other ingredients: Microcrystalline Cellulose, Lactose, Magnesium stearate, Sodium Laurylsulphate, Sodium starch glycolate.

Indications

Cardular is indicated in the treatment of

- Hypertension
- Benign Prostatic hyperplasia

Contraindications

Hypersensitivity to the active ingredient doxazosin or other quinazolines (such as prazosin, terazosin), hepatic diseases (hepatic insufficiency)

- No experience available on the usage of Cardular in children.

Special note: In Patients with heart failure (Cardiac insufficiency), doxazosin should be used only under periodic supervision of heart function.

Use in Pregnancy and Lactation

Cardular should not be used during Pregnancy or Lactation because clinical experience is not available. Animal experience did not reveal any teratogenic potential.

Adverse reactions

At the start of treatment adverse reactions may occur, which disappear in most cases with continued treatment or subside so that the patients can tolerate.

The following may occur: Circulatory disorders with tendency for blood pressure fall when changing positions for instance from lying to standing, rarely associated with syncope; dizziness, headache, fatigue, malaise, vertigo, asthenia, edema, dry mouth, palpitation, somnolence rhinitis and non-specific gastrointestinal side effects, rarely non-specific skin reactions. Extremely rare cases of urinary incontinence were reported. The following additional adverse events have been reported that are typical among patients treated for hypertension but it is not clear whether these can be attributed to the intake of Cardular like tachycardia, palpitation, chest pain, angina pectoris, myocardial infarction, cardiac arrhythmias and cerebrovascular accident. Isolated cases of priapism have been reported to be associated with alpha-1-antagonists, including doxazosin. In patients with benign Prostatic hyperplasia, a similar adverse event profile had been indicated in the controlled clinical trials.

Special note

After the start of treatment, circulatory disorders with a tendency for blood pressure fall when changing position may occur. Since such adverse reactions are more likely at higher doses than the recommended initial dose, dosage instructions should be carefully adhered to.

Effects on driving and operating machinery

Treatment with Cardular requires periodic medical check-up because of individually different reactions the ability to engage in activities such as operating machinery or driving motor vehicles may be impaired, especially when initiating therapy, upon drug switching and upon simultaneous alcohol consumption.

Drug interaction

Cardular potentiates the blood pressure lowering action of other antihypertensive drugs.

Dosage and duration of treatment

Unless otherwise prescribed the following dosage guidelines are recommended:

In benign Prostatic hyperplasia

Therapy should be initiated by Cardular 1 mg tablet once daily. The daily dosage should then be increased after one to two weeks to 2 mg doxazosin once daily and if necessary to 4 mg of doxazosin once daily as determined by patient response.

The maximum recommended dose is 8 mg of doxazosin once daily.

The following dosage schedule with Cardular 1 mg is recommended for the start of treatment:

1st to 8th day 1 Cardular 1 mg tablet (1 mg of doxazosin)
once daily

9st to 14th day 2 Cardular 1 mg tablet (2 mg of doxazosin)
once daily

Thereafter individual titration to the required maintenance dose.

For this purpose, tablets with 2 mg and 4 mg are available.

The usual dose is 2 - 4 mg once daily.

Doxazosin may be administered either in the morning or in the evening.

In Hypertension

The same as above. However, the maximum recommended dose of Doxazosin in hypertension is 16 mg once daily.

Mode of Administration

The tablet should be swallowed with some liquid.

Duration of Administration

There is no limit to the duration of administration.

Overdose

Should overdosage lead to hypotension, the patient should be immediately placed in a supine, head down position. Other supportive measures should be performed if thought appropriate in individual cases. Since doxazosin is highly protein bound, dialysis is not indicated.



Properties

In patients with symptomatic BPH, urodynamics and symptoms are improved by the use of Cardular. This effect is due to selective blockade of α_1 -receptors in muscles of prostate and neck of the bladder. Doxazosin has been shown to be an effective blocker of the I.A subtypes of the α_1 -adrenoreceptor which account over 70% of the subtypes in the Prostats. This accounts for B.P.H. Patients.

In hypertensives, blockage of α_1 -receptors in vascular muscles results in peripheral vasodilation. This leads to blood pressure reduction by means of a decrease in peripheral vascular resistance.

Tolerance has not been observed. Elevations of plasma renin activity and tachycardia were seen infrequently.

Clinical studies in hypertensives have shown that doxazosin produces slight plasma concentration reductions in triglycerides and total cholesterol as well as LDL fraction.

Treatment with Cardular has been shown to result in regression of left ventricular hypertrophy as well as an improved insulin sensitivity in patients with such impairment.

How supplied

Tablets 1 mg packs of 20

Tablets 2 mg packs of 20

Tablets 4 mg packs of 20

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HEINRICH MACK NACHF.,
Subsidiary of Pfizer,
Illertissen, Germany

This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

إن هذا الدواء

- الدواء مستعمل يؤثر على صحتك واستهلاكه خلافاً للتعليمات يعرضك للخطر
- اتبع بدقة وصفة الطبيب وطريقة الاستعمال المخصوص عليها وتعليمات الصيدلاني الذي صرفها لك
- فالطبيب والصيدلاني هما المختصان بالدواء ويضعونه
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك
- لا تكرر صرف الدواء بدون وصفة طبية

لا تشترك الأدوية في متناول أيدي الأطفال

مجلس وزراء الصحة العرب
اتحاد الصيدالفة العرب