



Alphapress®

(Doxazosin Mesylate)

PROPERTIES

In patients with symptomatic BPH, urodynamics and symptoms are improved by the use of doxazosin mesylate. This effect is due to selective alpha₁-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 alpha₁-adrenoreceptor which account over 70% of the subtypes in the prostates. This accounts for B.P.H. patients.

In hypertensive, blockage of alpha₁-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 hypertensive have shown that doxazosin produces slight plasma concentration reductions in triglycerides and total cholesterol as well as LDL fraction.

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

INDICATIONS

Alphapress® is indicated in the treatment of:

- Hypertension.
- Benign prostatic hyperplasia.

SIDE EFFECTS

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 doxazosin 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.

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 doxazosin in children.

PRECAUTIONS

In patients with heart failure (cardiac insufficiency), doxazosin should be used only under periodic supervision of heart function.

DRIVING AND OPERATING MACHINERY

Treatment with doxazosin 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.

PREGNANCY AND LACTATION

Pregnancy category (C).

Doxazosin should not be used during pregnancy or lactation because clinical experience is not available.

Animal experience did not reveal any teratogenic potential.

DRUG-DRUG INTERACTIONS

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

OVERDOSAGE

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.

DOSAGE AND ADMINISTRATION

Unless otherwise prescribed the following dosage guidelines are recommended:

In benign prostatic hyperplasia:

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

The maximum recommended dose is 8mg of Alphapress® once daily.

The following dosage schedule with Alphapress® is recommended for the start of treatment:

1st to 8th day 1 Alphapress® 1mg tablet, once daily.

9th to 14th day 1 Alphapress® 2mg tablet, once daily.

Thereafter individual titration to the required maintenance dose.

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

The usual dose is 2 - 4mg once daily.

Alphapress® may be administered either in the morning or in the evening.

In Hypertension:

The same as above. However, the maximum recommended dose of Alphapress® in hypertension is 16mg 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.

PRESENTATIONS

Alphapress® 1 tablets, each tablet contains doxazosin mesylate equivalent to 1 mg doxazosin in a pack of 20 tablets.

Alphapress® 2 tablets, each tablet contains doxazosin mesylate equivalent to 2 mg doxazosin in a pack of 20 tablets.

Alphapress® 4 tablets, each tablet contains doxazosin mesylate equivalent to 4 mg doxazosin in a pack of 20 tablets.

Alphapress® 8 tablets, each tablet contains doxazosin mesylate equivalent to 8 mg doxazosin in a pack of 20 tablets.

INACTIVE INGREDIENTS

Alphapress® 1,2,4:

Sodium Lauryl Sulphate, Sodium Starch Glycolate, Microcrystalline Cellulose, Lactose Monohydrate, Magnesium Stearate.

Alphapress® 8:

Sodium Lauryl Sulphate, Sodium Starch Glycolate, Microcrystalline Cellulose, Lactose Monohydrate, Magnesium Stearate, Crosscarmellose Sodium, Polyvinylpyrrolidone, Blue Color FD & C No.2.

STORAGE CONDITIONS

Store in a dry place below 30 °C.

This is a medication

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method of use and the instructions of pharmacist who sold the medication.
- 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 prescription without consulting your doctor.
- Keep out of reach of children.