

Terasin^{Tab.}

Terazosin HCl 2.374mg (2mg as Terazosin)

■ COMPOSITION

Each tablet contains 2.374mg of Terazosin hydrochloride (2mg as Terasoin).

■ INDICATIONS

Hypertension (mid-moderate)
Benign Prostatic Hyperplasia (BPH)

■ DOSAGE & ADMINISTRATION

Hypertension

Adults:

Initial dose

1 mg before bedtime is the starting dose for all patients and should not be exceeded. Compliance with this initial dosage recommendation should be strictly observed to minimise potential for acute first-dose hypotensive episodes.

Subsequent doses

The single daily dosage may be increased by approximately doubling the dosage at weekly intervals to achieve the desired blood pressure response.

The usual maintenance dose is 2mg to 10mg once daily. Doses over 20mg rarely improve efficacy and doses over 40mg have not been studied.

BPH

Adults Only:

The dose of terazosin should be adjusted according to the patient's response. The following is a guide to administration:

Initial dose

1 mg before bedtime is the starting dose for all patients and should not be exceeded. Strict compliance with this recommendation should be observed to minimise acute first-dose hypotensive episodes.

Subsequent dose

The dose may be increased by approximately doubling at weekly or bi-weekly intervals to achieve the desired reduction in symptoms. The maintenance dose is usually 5 to 10mg once daily. Improvements in symptoms have been detected as early as two weeks after starting treatment with terazosin.

At present there are insufficient data to suggest additional symptomatic relief with doses above 10mg once daily.

Use in renal insufficiency

Pharmacokinetic studies indicate that patients with impaired renal function need no alteration in the recommended dosages.

Use in Children

Use in children for BPH is not applicable.

Use in the Elderly

Pharmacokinetic studies in the elderly indicate that no alteration in dosage recommendation is required.

Postural Hypotension

Postural hypotension has been reported to occur in patients receiving terazosin for the symptomatic treatment of urinary obstruction caused by BPH. In these cases, the incidence of postural hypotensive events was greater in patients aged 65 years and over (5.6%) than those aged less than 65 years (2.6%).

Use with thiazide diuretics and other antihypertensive agents

When adding a thiazide diuretic or another antihypertensive agent to a patient's regimen the dose of Terazosin should be reduced and retitration carried out if necessary. Caution should be observed when Terazosin is administered with thiazides or other antihypertensive agents as hypotension may develop.

■ CONTRAINDICATIONS

Known hypersensitivity to alpha-adrenoreceptor antagonists.

■ DRUG INTERACTIONS

In patients receiving terazosin for BPH, plus ACE inhibitors or diuretics, the proportion reporting dizziness or related side effects was greater than in the total population of terazosin treated patients from clinical trials.

Caution should be observed when terazosin is administered with other antihypertensive agents, to avoid the possibility of significant hypotension. When adding terazosin to a diuretic or other antihypertensive agent, dosage reduction and retitration may be necessary.

Terazosin has been given without interaction with analgesics/anti-inflammatories, cardiac glycosides, hypoglycaemics, antiarrhythmics, anxiolytics/sedatives,

antibacterials, hormones/steroids and drugs used for gout.

Hypotension has been reported when terazosin has been used with phosphodiesterase-5 (PDE-5) inhibitors. Concomitant treatment with terazosin and sildenafil or vardenafil should only be initiated if the patient is stabilised on terazosin. In addition, vardenafil should not be administered within 6 hours of terazosin, and sildenafil should not be initiated within 4 hours of terazosin therapy.

■ PREGNANCY & LACTATION

Although no teratogenic effects were seen in animal testing, the safety during pregnancy and lactation has not yet been established. Terazosin should not be used therefore in pregnancy unless the potential benefit outweighs the risk.

■ ADVERSE REACTIONS

Terazosin, in common with other alpha-adrenoreceptor antagonists, may cause syncope. Syncopal episodes have occurred within 30 to 90 minutes of the initial dose of the drug. Syncope has occasionally occurred in association with rapid dosage increases or the introduction of another antihypertensive agent.

In clinical studies in hypertension, the incidence of syncopal episodes was approximately one percent. In most cases, this was believed to be due to an excessive postural hypotensive effect although occasionally the syncopal episode has been preceded by a bout of tachycardia with heart rates of 120 to 160 beats per minute.

If syncope occurs the patient should be placed in a recumbent position and given supportive treatment as necessary.

Dizziness, light-headedness or fainting may occur when standing up quickly from a lying or sitting position. Patients should be advised of this possibility and instructed to lie down if these symptoms appear and then sit for a few minutes before standing to prevent re-occurrence.

These adverse effects are self limiting and, in most cases, do not recur after the initial period of therapy or during subsequent titration.

Adverse events reported with terazosin

The most common events were asthenia, palpitations, nausea, peripheral oedema, dizziness, somnolence, nasal congestion/rhinitis and blurred vision/amblyopia.

In addition, the following have been reported: back pain; headache; tachycardia; postural hypotension; syncope; oedema; weight gain; pain in extremities; decreased libido; depression; nervousness; paraesthesia; vertigo; dyspnoea; sinusitis and impotence.

Additional adverse reactions reported in clinical trials or reported during marketing experience but not clearly associated with the use of terazosin include the following: chest pain; facial oedema; fever; abdominal pain; neck pain; shoulder pain; vasodilation; arrhythmia; constipation; diarrhoea; dry mouth; dyspepsia; flatulence; vomiting; gout; arthralgia; arthritis; joint disorders; myalgia; anxiety; insomnia; bronchitis; epistaxis; flu symptoms; pharyngitis; rhinitis; cold symptoms; pruritis; rash; increased cough; sweating; abnormal vision; conjunctivitis; tinnitus; urinary frequency; urinary tract infection and urinary incontinence primarily reported in post-menopausal women.

■ OVERDOSE

Should administration of terazosin lead to acute hypotension, cardiovascular support is of first importance. Restoration of blood pressure and normalisation of heart rate may be accomplished by keeping the patient in a supine position. If this measure is inadequate, shock should first be treated with volume expanders and, if necessary, vasopressors could then be used. Renal function should be monitored and general supportive measures applied as required. Dialysis may not be of benefit since laboratory data indicate that terazosin is highly protein bound.

■ STORAGE : Please store below 25 °C.

■ SHELF LIFE : 3 Years.

■ PACKAGE : 100 Tablets / box

This drug is manufactured in accordance with Korea Good Manufacturing Practice(KGMP) as recommended by WHO.