Ostan®

Losartan Potassium USP

Presentation :
Ostan® 50 : Each Film-coated tablet contains Losartan Potassium USP 50mg.
Ostan®25 : Each Film-coated tablet contains Losartan Potassium USP 25mg.

Description :
Ostan® (Losartan) exerts its antihypertensive effect by selectively antagonizing the binding of angiotensin II to the AT1 receptor, thereby inhibiting the vasoconstrictive effects of angiotensin II. Since the angiotensin converting enzyme is not affected, there is no potentiation of bradykinin as usually seen with inhibitors of the angiotensin converting enzyme. Therefore, cough or angioedema would not be expected with losartan use. Binding of losartan to the AT1 receptor is reversible and competitive.

Indication :
Ostan® (Losartan) is indicated for the treatment of all grades of hypertension.

Dosage and Administration :
The usual starting and maintenance dose is 50 mg once daily for most patients. The maximal antihypertensive effect is attained 3-6 weeks after initiation of therapy. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily.

Use in the elderly : Patients up to 75 years : No initial dosage adjustment is necessary for this group of patients.

Patients over 75 years : Presently there is limited clinical experience in this group; a lower starting dose of 25 mg once daily is recommended.

Use in renal impairment : No initial dosage adjustment is necessary in patients with mild renal impairment (i.e creatinine clearance 20-50 ml/min). For patients with moderate to severe renal impairment (i.e. creatinine clearance <20ml/min) or patients on dialysis, a lower starting dose of 25 mg once daily is recommended.

Use in patients with intravascular volume depletion : For the very small proportion of patients who have intravascular volume depletion (e.g. those treated with high-dose diuretics), a starting dose of 25 mg once daily is recommended.

Use in hepatic impairment : A lower dose should be considered for patients with history of hepatic impairment.

Ostan® may be administered with other anithypertensive agents.
Ostan® may be administered with or without food.

Contra-indications :
Losartan is contra-indicated in pregnancy and in patients who are hypersensitive to any component of this product.

Side effects :
Side effects have usually been mild and transient in nature and have not required discontinuation of therapy. The overall incidence of side effects reported with losartan was comparable to placebo.
In controlled clinical trials for essential hypertension, dizziness was the only side effect reported as drug related that occurred with an incidence greater than placebo in 1% or more of patient treated with losartan. In addition, dose-related orthostatic effects were seen in less than 1% of patients. Rarely, rash was reported, although the incidence in controlled clinical trials was less than placebo.

Acute overdose :
Limited data are available in regard to overdose in humans. The most likely manifestation of overdose would be hypertension and tachycardia; bardycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypertension should occur, supportive treatment should be instituted.

Use in pregnancy and lactation :
Use in pregnancy : Although there is no experience with the use of losartan in pregnant women, animal studies with losartan potassium have demonstrated fetal and neonatal injury and death, the mechanism of which is believed to be pharmacologically medicated through effects on the renin-angiotensin-aldosterone system.
Use in lactation : It is not known whether losartan is excreted in human milk. However, significant levels of losartan and the active metabolite were shown to be present in rat milk. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue breast-feeding or discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interactions :
No drug interactions of clinical significance have been identified. Compounds which have been studied in clinical pharmacokinetic trials include hydrochlorothiazide, digoxin, warfarin, cimetidine, ketoconazole and phenobarbital.

Storage Condition :
Store in a cool and dry place, away from light and children.

Package quantities :
Ostan® 50 : Box containing 3 x 10, 5 x 10 tablets in blister pack.
Ostan® 25 : Box containing 3 x 10 tablets in blister pack.

Manufactured by:
RENATA LIMITED
Mirpur, Dhaka, Bangladesh
® Trade Mark
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