گولیاں

# لوٹینس®

لوذارٹن پوٹاشیم یو۔ایس۔پی ۲۵ ملی گرام، ۵۰ ملی گرام

## دافع بلند فشار خون

### خوراک:

**لوٹینس** کی عمومی ابتدائی خوراک ۵۰ ملی گرام روزانہ دن میں ایک مرتبہ جو کہ مریض کی انفرادی اثر پزیری پر انحصار کرتے ہوئے ۱۰۰ ملی گرام روزانہ تک بڑھائی جا سکتی ہے۔ یہ گولیاں کھانے کے ساتھ یا کھانے کے بغیر بھی لی جا سکتی ہیں۔

### ہدایات:

- دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
- دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
- یہ دوا صرف ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
- تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

### پیشکش:

**لوٹینس ۲۵** ملی گرام فلم کوٹڈ گولیاں (۲×۱۰) ایلو۔ایلو پیک میں دستیاب ہیں۔
**لوٹینس ۵۰** ملی گرام فلم کوٹڈ گولیاں (۲×۱۰) ایلو۔ایلو پیک میں دستیاب ہیں۔

*Manufactured by:*
**Schazoo Zaka (Pvt) Ltd.**
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

# Lotense®

**Tablets**

Losartan Potassium U.S.P. **25mg, 50mg**

### COMPOSITION:
Each film coated tablet contains:
Losartan Potassium U.S.P. ..... 25 mg.
Losartan Potassium U.S.P. ..... 50 mg.

### CLINICAL PHARMACOLOGY:
**Lotense** (Losartan potassium), the first of a new class of agents for the treatment of hypertension, is an angiotensin II receptor (type $AT_1$) antagonist. Angiotensin II is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by adrenal cortex. Losartan and its principle active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the $AT_1$ receptor found in many tissues.There is also an $AT_2$ receptor found in many tissues but it is not known to be associated with cardiovascular homeostasis. Both losartan and its principle active metabolite do not exhibit any partial agonist activity at the $AT_1$ receptor and have much greater affinity for the $AT_1$ receptor than for the $AT_2$ receptor.

### INDICATIONS:
**Lotense** is indicated for the treatment of hypertension.

### DOSAGE & ADMINISTRATION:
The usual starting and maintenance dose is 50 mg once daily for most patients. The maximum antihypertensive effect is attained in 3-6 weeks after initiation of therapy. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily. For patients with intravascular volume-depletion (e.g. those treated with high dose diuretics), a starting dose of 25 mg once daily should be considered. No initial dosage adjustment is necessary for elderly patients or for patients with renal impairment, including patients on dialysis. A lower dose should be considered for patients with a history of hepatic impairment. Losartan may be administered with other antihypertensive agents. Losartan may be administered with or without food.

### CONTRA-INDICATIONS:
Losartan is contra-indicated in patients who are hypersensitive to any component of this product.

### PRECAUTIONS:
**Hypotension and electrolyte/fluid imbalance:**
In intravascularly volume-depleted patients (e.g., those treated with high-dose diuretics), symptomatic hypotension may occur. These conditions should be corrected prior to administration of Losartan, or a lower starting dose should be used.

**Liver function impairment:**
Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a lower dose should be considered for patients with a history of hepatic impairment.

**Renal function impairment:**
As a consequence of inhibiting the renin-angiotensin system, changes in renal function including renal failure have been reported. In susceptible individuals, these changes in renal function may be reversible upon discontinuation of therapy.

**Pregnancy:**
When used during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death in the developing fetus. Hence when pregnancy is detected, Losartan should be discontinued as soon as possible.

**Nursing mothers:**
Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug , taking into account the importance of the drug to the mother.

**Pediatric use:**
Safety and effectiveness in children have not been established.

**Use in the elderly:**
In clinical studies there was no age-related difference in the efficacy or safety profile of losartan.

### DRUG INTERACTIONS:
In clinical pharmacokinetic trials, no drug interactions of clinical significance have been identified with hydrochlorothiazide, digoxin, warfarin, cimetidine, phenobarbital, ketoconazole and erythromycin. Rifampin and fluconazole have been reported to reduce levels of active metabolite.

The clinical consequences of these interactions have not been evaluated. As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics [e.g., spironolactone, triamterene, amiloride], potassium supplements, or salt subsitutes containing potassium may lead to increase in serum potassium concentration. As with other antihypertensive agents, the antihypertensive effect of losartan may be attenuated by the non-steroidal anti-inflammatory drug indomethacin.

### SIDE EFFECTS:
Generally Losartan has been found well tolerated in controlled clinical trials for hypertension. Side effects have usually been mild and transient in nature and have not required discontinuation of therapy. In controlled clinical trails, dizziness is the only side effect. Rarely, rash is reported.
The additional side effects are;

**Hypersensitivity:** Anaphylactic reactions, angioedema including swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx and /or tongue has been reported rarely in patient treated with losartan.

**Gastrointestinal:** Hepatitis (reported rarely), liver function abnormalities.

**Hematologic:** Anemia.

**Musculoskeletal:** Myalgia.

**Nervous system / psychiatric:** Migraine.

**Respiratory:** Cough.

**Skin:** Urticaria, Pruritus.

### OVERDOSAGE:
Limited data is available in regard to overdosage in humans. The most likely manifestation of overdosage would be hypotension and tachycardia, bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension occur, supportive treatment should be instituted. Neither losartan nor the active metabolite can be removed by hemodialysis.

### STORAGE CONDITIONS:
* Store in a cool and dry place.
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

### PACKING:
**Lotense** 25 mg film coated tablets are available in (2x10) Alu-Alu pack.
**Lotense** 50 mg film coated tablets are available in (2x10) Alu-Alu pack.