ViSARTAN

Losartan Potassium Tablets USP 50 mg

COMPOSITION:
Each film-coated tablet contains:
Losartan Potassium USP.....50 mg
Excipients .....q.s.
Approved color used.

PHARMACEUTICAL FORM:
Film-coated tablet

1. What Visartan is and what it is used for:
Visartan is used for the treatment of essential hypertension in adults, and in children and adolescents aged 6 to 18 years. Treatment of chronic heart failure in adult patients when treatment with angiotensin-converting enzyme (ACE) inhibitors is not considered appropriate due to incompatibility—specifically cough—or contraindication.

2. What you need to know before using Visartan:
Do not take Visartan:
If you have hypersensitivity to the active substance or to any of the listed excipients. During the 2nd and 3rd trimesters of pregnancy. In cases of severe hepatic impairment. Concomitant use of Losartan potassium with products containing aliskiren is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73m²).

3. Warnings and precautions:
Angioedema: Patients with a history of angioedema (swelling of the face, lips, throat, and/or tongue) should be closely monitored. Symptomatic hypotension—particularly after the first dose and after dose increases—may occur in patients with sodium depletion due to vigorous diuretic therapy, dietary salt restriction, diarrhea, or vomiting. Visartan may cause death or serious injury to the fetus when taken during the last 6 months of pregnancy.

4. Other medicines and Visartan:
Other antihypertensive agents may increase the hypotensive action of losartan. Concomitant use of other substances that may induce hypotension as an adverse reaction (such as tricyclic antidepressants, antipsychotics, baclofen, and amifostine) may increase the risk of hypotension. Visartan is metabolized primarily by cytochrome P450 (CYP) 2C9 into the active carboxylic acid metabolite. In a clinical trial, it was found that fluconazole (a CYP2C9 inhibitor) decreased exposure to the active metabolite by approximately 50%. Concomitant treatment with losartan and rifampin (a metabolic enzyme inducer) resulted in a 40% reduction in the plasma concentration of the active metabolite.

5. Pregnancy and Breastfeeding:
Pregnancy: The use of Visartan is not recommended during the first trimester of pregnancy. The use of Visartan is contraindicated during the second and third trimesters of pregnancy. Visartan should not be initiated during pregnancy. Unless continued therapy with losartan is considered essential, patients planning to become pregnant should switch to alternative antihypertensive treatments that have an established safety profile for use during pregnancy. When pregnancy is diagnosed, treatment with losartan should be discontinued immediately, and, if appropriate, an alternative treatment should be instituted.
Breastfeeding: As there is no information available regarding the use of losartan during breastfeeding, it is not recommended; alternative treatments with better-established safety profiles for use during breastfeeding are preferable, particularly when nursing newborns or premature infants.

6. Driving and Using Machines:
No studies have been conducted regarding the effects on the ability to drive and use machines.

7. How to Take Visartan
Route of Administration: Oral
Visartan tablets should be swallowed whole with a glass of water. Visartan may be administered with or without food.
Special Populations:
Use in patients with intravascular volume depletion: For patients with intravascular volume depletion (e.g., those treated with high-dose diuretics), an initial dose of 25 mg once daily should be considered. **Use in patients with renal impairment and patients on hemodialysis:** No initial dosage adjustment is required in patients with renal impairment or in patients undergoing hemodialysis.
Use in patients with hepatic impairment: Lower doses should be considered in patients with a history of hepatic impairment. There is no therapeutic experience in patients with severe hepatic impairment. Therefore, losartan is contraindicated in patients with severe hepatic impairment.
Pediatric population:
6 months to less than 6 years: The safety and efficacy in children aged 6 months to less than 6 years have not been established.
6 to 18 years: For patients able to swallow tablets, the recommended dose is 25 mg once daily for patients weighing between 20 and 50 kg. (In exceptional cases, the dose may be increased up to a maximum of 50 mg once daily). Dosage should be adjusted based on blood pressure response.
Use in the elderly: Although consideration should be given to initiating treatment with 25 mg in patients over 75 years of age, dosage adjustment is generally not required in the elderly. Visartan tablets are available in 25 mg, 50 mg, and 100 mg strengths.

8. Adverse Reactions:
Immune System Disorders
Hypersensitivity, anaphylactic reactions, angioedema, and vasculitis.
Nervous System Disorders
Dizziness, drowsiness, headache, paresthesia, migraine.
Cardiac Disorders
Palpitations, angina pectoris, syncope, atrial fibrillation, cerebrovascular accident (stroke).
Gastrointestinal Disorders
Abdominal pain, nausea, vomiting.
Renal and Urinary Disorders
Renal insufficiency, renal failure.

9. How to Store Visartan:
Store below 30°C in a dry place. Protect from light.

WARNING:
Keep this medicine out of the reach of children.

10. Presentation:
Visartan is available in a box containing 6 x 10 tablets.

Manufactured by:

US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in

Artcode