Azilpres™

Azilsartan Medoxomil

Presentation:
Azilpres™ 40: Each film coated tablet contains Azilsartan Medoxomil Potassium INN equivalent to Azilsartan Medoxomil 40mg.
Azilpres™ 80: Each film coated tablet contains Azilsartan Medoxomil Potassium INN equivalent to Azilsartan Medoxomil 80mg.

Description:
Azilsartan is a Angiotensin II receptor blocker (ARB) used to treat high blood pressure (hypertension) in adults. It is an orally administered prodrug that is rapidly converted by esterases during absorption to the active moiety, Azilsartan. Azilsartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Azilsartan has more than a 10,000-fold greater affinity for the AT1 receptor than for the AT2 receptor which is not known to be associated with cardiovascular homeostasis. Azilsartan does not inhibit Angiotensin converting enzyme (ACE) so it does not affect bradykinin. It does not bind to or block other receptors or ion channels known to be important in cardiovascular regulation.

Indication and usage:
Azilsartan is indicated for the treatment of hypertension, either alone or in combination with other antihypertensive agents.

Dosage & Administration:
Recommended dose in adults: 80 mg once daily with or without food. A starting dose of 40 mg can be considered for patients who are treated with high doses of diuretics. If blood pressure is not controlled with Azilsartan alone, additional antihypertensive agents may be needed.

Side-effects:
In several clinical trials treatment with Azilsartan was found well-tolerated. The most common side effects are-Hypotension/orthostatic hypotension, nausea, asthenia, fatigue, muscle spasm, dizziness and diarrhea

Precautions:
• Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women during the second and third trimester. When pregnancy is detected, Azilsartan should be discontinued as soon as possible.

• Symptomatic hypotension may occur in patients treated with high doses of diuretics. Volume or salt depletion should be corrected prior to administration of Azilsartan or treatment should be started with 40 mg daily.

Contraindications
There is no contraindication reported for treatment with Azilsartan.

Use in specific population:
Pregnancy
Pregnancy Category C (first trimester) and D (second and third trimesters). There is no clinical experience with the use of Azilsartan in pregnant women.

Nursing Mothers
It is not known if Azilsartan is excreted in human milk, but it is excreted at low concentrations in the milk of lactating rats. 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 pediatric patients under 18 years of age have not been established.

Geriatric Use
No dose adjustment with Azilsartan is necessary in elderly patients. High serum creatinine was reported in patients aged 75 or older. No other differences in safety or effectiveness were observed between elderly patients and younger patients.

Renal Impairment
Dose adjustment is not required in patients with mild-to-severe renal impairment or end-stage renal disease.

Hepatic Impairment
No dose adjustment is necessary for subjects with mild or moderate hepatic impairment. Azilsartan has not been studied in patients with severe hepatic impairment

Drug Interaction:
• No clinically significant drug interactions have been observed in studies of Azilsartan given with amlodipine, antacids, chlorthalidone, digoxin, fluconazole, glyburide, ketoconazole, metformin, pioglitazone, and warfarin. Therefore, Azilsartan may be used concomitantly with these medications.

• The antihypertensive effect of angiotensin II receptor antagonists, including Azilsartan, may be attenuated by NSAIDs, including selective COX-2 inhibitors.

Overdose: Limited data are available related to overdosage in humans. During clinical trials in healthy subjects, once daily doses up to 320 mg of Azilsartan were administered for 7 days and were well tolerated. In the event of an overdose, supportive therapy should be instituted as dictated by the patient's clinical status. Azilsartan is not dialyzable.

Storage: Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack
Azilpres™ 40: Each box contains 3 Alu-Alu blister strips of 10 tablets.
Azilpres™ 80: Each box contains 2 Alu-Alu blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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