Adarbi®

Azilsartan Medoxomil

COMPOSITION

Adarbi 40 Tablet: Each tablet contains Azilsartan Kamedoxomil INN equivalent to Azilsartan Medoxomil 40 mg.
Adarbi 80 Tablet: Each tablet contains Azilsartan Kamedoxomil INN equivalent to Azilsartan Medoxomil 80 mg.

PHARMACOLOGY

Adarbi (Azilsartan Medoxomil), a prodrug, is hydrolyzed to Azilsartan in the gastrointestinal tract during absorption. Azilsartan is a selective AT_1 subtype angiotensin II receptor antagonist. Azilsartan blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland.

INDICATION

Adarbi (Azilsartan Medoxomil) is indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily stroke and myocardial infarction. **Adarbi** (Azilsartan Medoxomil) may be used either alone or in combination with other antihypertensive agents.

DOSAGE AND ADMINISTRATION

The recommended dose in adults is 80 mg taken orally once daily. Consider a Starting dose of 40 mg for patients who are treated with high doses of diuretics.
If blood pressure is not controlled with **Adarbi** alone, additional blood pressure reduction can be ahieved by taking **Adarbi** with other antihypertensive agents.

CONTRAINDICATION

It is contraindicated to co-administer Aliskiren with Azilsartan in patients with Diabetes.

WARNING AND PRECAUTION

Use of Azilsartan Medoxomil during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. In patients who are intravascularly volume-depleted (e.g., those treated with high-dose diuretics), symptomatic hypotension may occur. Changes in renal function including renal failure has been reported in renal impaired patient.

SIDE EFFECT

The most common adverse reaction in adults is diarrhea. The other side effects are nausea, asthenia, fatigue, muscle spasm, dizziness and cough.

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. The risk to the fetus increases if Azilsartan Medoxomil is administered during the second or third trimesters of pregnancy. It is not known whether Azilsartan Medoxomil is excreted in human milk, as many drugs are excreted in human milk and 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.

USE IN CHILDREN

Safety and effectiveness in pediatric patients under 18 years of ages have not been established.

DRUG INTERACTION

No drug interactions have been observed in studies of Azilsartan Medoxomil or Azilsartan given with amlodipine, antacids, chlorthalidone, digoxin, fluconazole, glyburide, ketoconazole, metformin, pioglitazone and warfarin. The antihypertensive effect of Azilsartan may be attenuated by the non-steroidal anti-inflammatory drugs including selective COX-2 inhibitors. Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors or aliskiren is associated with increased risks of hypotension, hyperkalemia and changes in renal function.

OVERDOSE

Limited data are available related to overdose in humans. In the event of and overdose, supportive therapy should be instituted as dictated by the patient's clinical status. Azilsartan is not dialyzable.

STORAGE CONDITION

keep in a dry place away from light and heat. Keep out of the reach of children.

HOW SUPPLIED

Adarbi 40 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.
Adarbi 80 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Comilla, Bangladesh.