LUPIN®

NEW

The first AB rated

generic equivalent to Edarbi®*

Azilsartan Medoxomil Tablets

Rx Only | *Edarbi is a registered trademark of Takeda Pharmaceutical Company Limited

NDC	Strength	Pack Size
70748-236-06	40 mg	30 tablets
70748-237-06	80 mg	30 tablets

WARNING: FETAL TOXICITY

See full Prescribing Information for complete boxed warnings.

- When pregnancy is detected, discontinue azisartan medoxomil tablets as soon as possible.
- Drugs that act directly on the renin-angiotensin system can cause injury and death to developing fetus

IMPORTANT SAFETY INFORMATION

INDICATIONS

Azilsartan medoxomil tablets is an angiotensin II receptor blocker (ARB) indicated for the treatment of hypertension in adults, to lower blood pressure. Azilsartan medoxomil tablets may be used either alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. There are no controlled trials demonstrating risk reduction with Azilsartan medoxomil tablets. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC). Azilsartan medoxomil tablets may be used with other antihypertensive agents.

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- **When pregnancy is detected, discontinue azilsartan medoxomil tablets as soon as possible.**
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.**

WARNINGS AND PRECAUTIONS

Do not coadminister aliskiren-containing products with azilsartan medoxomil tablets in patients with diabetes.

Fetal Toxicity:

Azilsartan medoxomil tablets can cause fetal harm when administered to a pregnant woman. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue azilsartan medoxomil tablets as soon as possible.

Hypotension in Volume - or Salt-Depleted Patients:

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of treatment with azilsartan medoxomil tablets. Correct volume or salt depletion prior to administering azilsartan medoxomil tablets, or start treatment at 40 mg. If hypotension does occur, the patient should be placed in the supine position and, if necessary, given an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

Impaired Renal Function:
Monitor for worsening renal function in patients with renal impairment. As a consequence of inhibiting the renin-angiotensin system, changes in renal function may be anticipated in susceptible individuals treated with azilsartan medoxomil tablets. In patients whose renal function may depend on the activity of the renin-angiotensin system (e.g., patients with severe congestive heart failure, renal artery stenosis, or volume depletion), treatment with angiotensin-converting enzyme inhibitors and angiotensin receptor blockers has been associated with oliguria or progressive azotemia and rarely with acute renal failure and death. Similar results may be anticipated in patients treated with azilsartan medoxomil tablets.

In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported. There has been no long-term use of azilsartan medoxomil in patients with unilateral or bilateral renal artery stenosis, but similar results are expected.

ADVERSE REACTIONS (AEs):
- The most common AE that occurred more frequently with azilsartan medoxomil tablets than placebo in adults was diarrhea (2% vs 0.5%).

DRUG INTERACTIONS:
- Monitor renal function periodically in patients receiving azilsartan medoxomil and NSAIDs who are also elderly, volume-depleted (including those on diuretics), or who have compromised renal function, as deterioration of renal function, including possible acute renal failure, may result. These effects are usually reversible. NSAIDs may reduce the antihypertensive effect of azilsartan medoxomil.
- Dual blockade of the renin-angiotensin system (RAS) with angiotensin receptor blockers, ACE inhibitors or aliskiren is associated with increased risks of hypotension, hyperkalemia and changes in renal function (including acute renal failure) compared to monotherapy. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function and electrolytes in patients on azilsartan medoxomil tablets and other agents that affect the RAS. Do not coadminister aliskiren with azilsartan medoxomil tablets in patients with diabetes or renal impairment (GFR <60 mL/min).
- Increases in serum lithium concentrations and lithium toxicity have been reported during concomitant administration of lithium with angiotensin II receptor agonists. Monitor serum lithium levels during concomitant use.

The Important Safety Information does not include all the information needed to use azilsartan medoxomil tablets safely and effectively.

For further information, please see complete Prescribing Information for azilsartan medoxomil tablets.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.