



## Azilsartan Medoxomil

**Adarbi** (Azilsartan Medoxomil), a prodrug, is hydrolyzed to Azilsartan in the gastrointestinal tract during absorption. Azilsartan is a selective AT<sub>1</sub> 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<sub>1</sub> receptor in many tissues, such as vascular smooth muscle and the adrenal gland.

### **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.

### **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 achieved by taking Edarbi with other antihypertensive agents.

### **SIDE EFFECT**

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

### **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.

### **CONTRAINDICATION**

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

### **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.

### **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.

### **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 10 tablets in Alu-Alu blister pack.

