

Abetis[®]

Olmesartan Medoxomil USP

Composition

Abetis[®] 10 tablet: Each coated tablet contains Olmesartan Medoxomil USP 10 mg.

Abetis[®] 20 tablet: Each coated tablet contains Olmesartan Medoxomil USP 20 mg.

Abetis[®] 40 tablet: Each coated tablet contains Olmesartan Medoxomil USP 40 mg.

Pharmacology

Abetis[®] is the preparation of Olmesartan Medoxomil which is a selective AT₁ subtype angiotensin II receptor antagonist. Olmesartan Medoxomil blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor in vascular smooth muscle. Its action is, therefore, independent of the pathways for angiotensin II synthesis.

Indication

Abetis[®] is indicated for the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Dose and administration

Route of administration: **Abetis[®]** should be taken in oral route.

Indication	Starting dose	Dose range
Adult hypertension	20 mg once daily	20 to 40 mg once daily
Pediatric hypertension (6 years of age and older)	20 kg to < 35 kg: 10 mg once daily	20 kg to < 35 kg: 10 to 20 mg once daily
	≥ 35 kg: 20 mg once daily	≥ 35 kg: 20 to 40 mg once daily

Abetis[®] may be administered with or without food. If blood pressure is not controlled by **Abetis[®]** alone, a diuretic may be added. **Abetis[®]** may be administered with other antihypertensive agents.

Hepatic impairment

The maximum dose in patients with moderate hepatic impairment is 20 mg daily. **Abetis[®]** is not recommended in patients with severe hepatic impairment.

Renal impairment

The maximum dose in patients with renal impairment is 20 mg daily if eGFR 20–60 ml/minute/1.73 m². **Abetis[®]** is not recommended in patients with severe renal impairment.

Contraindication

It is contraindicated in patient with known hypersensitivity to olmesartan medoxomil or any components of this product. It is also contraindicated in patients with biliary obstruction.

Warning and precaution

Angiotensin II receptor antagonist should be used with caution in patients with severe congestive heart failure. Caution should be taken with an activated renin-angiotensin-aldosterone system, such as volume and/or salt-depleted patients. Serum potassium should be monitored during treatment.

Side effects

The most common side effects are headache, influenza-like symptoms and dizziness.

Use in pregnancy and lactation

Pregnancy: 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. When pregnancy is detected, discontinue olmesartan medoxomil as soon as possible.

Lactation: It is not known whether olmesartan medoxomil is excreted in human milk. 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 and adolescents

Olmesartan medoxomil has not been shown to be effective for hypertension in children < 6 years of age. Children < 1 year of age must not receive olmesartan medoxomil for hypertension.

Drug interaction

Drug interaction with medication: The blood pressure lowering effect of olmesartan can be increased by concomitant use of other antihypertensive medications. Use of potassium sparing diuretics, potassium supplements and salt substitutes containing potassium or other drugs that may increase serum potassium levels (e.g., heparin) may lead to increases in serum potassium, such concomitant use is therefore not recommended. Concomitant use with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²).

Drug interaction with food and others: Not applicable.

Overdose

In case of overdose, hypotension and tachycardia; bradycardia could be encountered if parasympathetic stimulation occurs. If symptomatic hypotension occurs, initiate supportive treatment. The dialyzability of olmesartan medoxomil is unknown.

Storage

Store below 30°C in a dry place, protected from light. Keep away from the reach of children.

Packing

Abetis® 10 tablet: Carton of 70 tablets in blister pack.

Abetis® 20 tablet: Carton of 70 tablets in blister pack.

Abetis® 40 tablet: Carton of 70 tablets in blister pack.

® Registered Trade Mark



**Advanced Chemical
Industries PLC.**

7, Hajeegonj Road, Godnyl
Narayanganj, Bangladesh