

Only for the use of Medical Professionals

Abetis®

Olmesartan Medoxomil

Description

Abetis® is a preparation of Olmesartan Medoxomil; it is a selective angiotensin II receptor (subtype AT₁) antagonist. Olmesartan Medoximil 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.

Indications

Abetis® is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Dosage and administration

Adults:

Dosage must be individualized. The usual initial dose is 10 mg once daily. In patients whose blood pressure is not adequately controlled at this dose, the dose may be increased to 20 mg once daily as the optimal dose. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Abetis® may be increased to 40 mg. Doses above 40 mg do not appear to have greater effect.

Elderly and renal impairment:

The maximum dose in elderly and patients with mild to moderate renal impairment is 20 mg once daily.

Children and adolescents:

The safety and efficacy have not been established in children and adolescents up to 18 years of age.

Use in pregnancy and lactation

There is no experience with the use of Olmesartan Medoximil in pregnant women. However, drugs that act directly on the renin-angiotensin system administered during the second and third trimesters of pregnancy have been reported to cause foetal and neonatal injury and even death to the developing fetus. So it is probably best to avoid using the drug when pregnancy is detected. Olmesartan is excreted in

the milk of lactating rats but it is not known whether Olmesartan is excreted in human milk. Mothers must not breast-feed if they are taking Olmesartan Medoximil.

Side-effects

In general, the side-effects are usually mild although in a small undesired events have been reported, such as dizziness, vertigo, hypotension (rare), tachycardia, abdominal pain, diarrhea, dyspepsia, gastroenteritis, nausea, bronchitis, cough, pharyngitis, rhinitis, rash , angio-oedema (rare), arthritis (arthralgia), back pain, myalgia, haematuria, urinary tract infection, hyperlipidemia, hyperuricemia, hyperkalaemia, chest pain, fatigue, influenza-like symptoms and peripheral oedema.

Contraindications

Olmesartan Medoximil is contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients.

Precautions

Angiotensin II receptor antagonist (Olmesartan Medoximil) should be used with caution in patients with impaired renal function and renal artery stenosis; patients with aortic or mitral valve stenosis and obstructive hypertrophic cardiomyopathy. The use of Olmesartan Medoximil is not recommended in patients with hepatic impairment, since there is limited experience in this patient group.

Drug Interactions

No significant drug interactions were reported when Olmesartan Medoximil was co-administered with digoxin or warfarin. The blood pressure lowering effect of Olmesartan Medoximil 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.

Overdosage

Only limited information is available regarding overdosage in humans although the most likely effect of overdosage is hypotension. If overdosage is occurred, the patient should be carefully monitored and treatment should be symptomatic and supportive.

Pharmaceutical precautions

Store in a cool dry place. Protect from light.

Presentation

Abetis[®] 10 tablet: A round, light yellow colored film coated tablet. Each tablet contains Olmesartan Medoxomil INN 10mg.

Abetis[®] 20 tablet: A round, light yellow colored film coated tablet, break line in one side and other side plain. Each tablet contains Olmesartan Medoxomil INN 20mg.

Abetis[®] 40 tablet: A round, light yellow colored film coated tablet. Each tablet contains Olmesartan Medoxomil INN 40mg.

Package quantities

Abetis[®] 10 tablet: Carton of 30 tablets in Alu-PVC blister.

Abetis[®] 20 tablet: Carton of 30 tablets in Alu-PVC blister.

Abetis[®] 40 tablet: Carton of 30 tablets in Alu-PVC blister.

® Registered Trade Mark



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