

Olmesan[®]

Olmesartan Medoxomil 10 mg, 20 mg and 40 mg Tablet

Description

Olmesan[®] is a preparation of Olmesartan Medoxomil. It is an angiotensin II receptor antagonist (AT1 subtype). Olmesartan Medoxomil, a prodrug, is hydrolyzed to olmesartan during absorption from gastrointestinal tract.

Mode of Action

Olmesartan medoxomil is a potent, orally active, selective angiotensin II receptor (type AT1) antagonist. It is expected to block all actions of angiotensin II mediated by the AT1 receptor, regardless of the source or route of synthesis of angiotensin II. The selective antagonism of the angiotensin II (AT1) receptors results in increases in plasma renin levels and angiotensin I and II concentrations, and some decrease in plasma aldosterone concentrations.

Angiotensin II is the primary vasoactive hormone of the renin-angiotensin-aldosterone system and plays a significant role in the pathophysiology of hypertension via the type 1 (AT1) receptor.

Indications

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

Dosage and Administration

Dosage must be individualized. The usual recommended starting dose of Olmesartan Medoxomil 20 mg once daily when used as monotherapy in patients who are not volumecontracted. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmesartan Medoxomil may be increased to 40 mg. Doses above 40 mg do not appear to have greater effect. Twice-daily dosing offers no advantage over the same total dose given once daily.

Hepatic Impairment

Dose should not exceed 20 mg daily in moderate impairment. Manufacturer advises avoid in severe impairment—no information available.

Renal Impairment

Max. 20 mg daily if eGFR 20–60 mL/minute/1.73 m². Avoid if eGFR less than 20 mL/minute/1.73 m².

Contraindications

Olmesartan Medoxomil is contraindicated in patients who are hypersensitive to any component of this product.

Special Warnings and Precautions

Fetal/Neonatal Morbidity and Mortality

Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature of patients who were taking angiotensin converting enzyme inhibitors. When pregnancy is detected, Olmesartan Medoxomil should be discontinued 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 Olmesartan Medoxomil. Treatment should start under close medical supervision. If hypotension does occur, the patient should be placed

in the supine position and, if necessary, given an intravenous infusion of normal saline.

Drug Interactions

No significant drug interactions were reported in studies in which Olmesartan Medoxomil was co-administered with digoxin or warfarin in healthy volunteers. The bioavailability of Olmesartan was not significantly altered by the co-administration of antacids [Al(OH)₃/Mg(OH)₂]. Olmesartan Medoxomil is not metabolized by the cytochrome P450 system and has no effects on P450 enzymes; thus, interactions with drugs that inhibit, induce or are metabolized by those enzymes are not expected.

Use during Pregnancy and Lactation

Pregnancy

Pregnancy Categories C (first trimester) and D (second and third trimesters).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin receptor blocker therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Angiotensin II antagonists therapy exposure during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalemia).

Should exposure to angiotensin II antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken angiotensin II antagonists should be closely observed for hypotension.

Lactation

It is not known whether Olmesartan is excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. 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 Special Population

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Of the total number of hypertensive patients receiving Olmesartan Medoxomil in clinical studies, more than 20% were 65 years of age and over, while more than 5% were 75 years of age and older. No overall differences in effectiveness or safety were observed between elderly patients and younger patients.

Adverse Reactions

Common or very common

Arthritis, chest pain, cough, fatigue, gastro-intestinal disturbances, haematuria, hypertriglyceridaemia, hyperuricaemia, influenza-like symptoms, musculoskeletal pain, peripheral edema, pharyngitis, rhinitis, urinary-tract infection.

Uncommon

Angina, rash, vertigo.

Very rare

Headache, myalgia, pruritus, thrombocytopenia, urticaria.

Overdose

Only limited information is available regarding overdosage in humans. The most likely effect of overdosage is hypotension. In the event of overdosage, the patient should be carefully monitored and treatment should be symptomatic and supportive. No information is available regarding the dialysability of olmesartan.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in the original package in a cool & dry place. Protect from light and moisture.

Commercial Pack

Olmesan[®] 10 Tablet: Box containing 30 tablets. Each tablet contains Olmesartan Medoxomil INN 10 mg.

Olmesan[®] 20 Tablet: Box containing 30 tablets. Each tablet contains Olmesartan Medoxomil INN 20 mg.

Olmesan[®] 40 Tablet: Box containing 30 tablets. Each tablet contains Olmesartan Medoxomil INN 40 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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