Olpres

Olmesartan Medoxomil BP

Composition
Olpres 10 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 10 mg.
Olpres 20 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 20 mg.
Olpres 40 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 40 mg.

Description
Olpres is a preparation of Olmesartan Medoxomil, which is a selective angiotensin receptor (subtype AT1) antagonist. Olmesartan 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
Olpres 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 recommended starting dose of **Olpres** is 10 to 20 mg once daily when used as monotherapy. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of **Olpres** may be increased to 20 to 40 mg. Maximum recommended daily dose is 40 mg.

Children and adolescents (6 to 16 years of age): For children who can swallow tablets, the usual recommended starting dose of Olpres is 10 mg once daily for patients who weight 20 to < 35 kg (44 to 77 lb), or 20 mg once daily for patients who weight ≥ 35 kg. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of **Olpres** may be increased to a maximum of 20 mg once daily for patients who weigh < 35 kg or 40 mg once daily for patients who weight ≥ 35 kg. Children < 1 year of age must not receive **Olpres** for hypertension.

Elderly and renal impairment: No initial dosage adjustment is recommended for elderly patients. No initial dosage adjustment is recommended for patients with moderate to marked renal impairment (creatinine clearance < 40 ml/min. For patients with possible depletion of intravascular volume (e.g., patients treated with diuretics, particularly those with impaired renal function), initiate **Olpres** under close medical supervision and give consideration to use of a lower starting dose.

Side effects
Treatment with Olmesartan is generally well tolerated, with an incidence of side effects similar to placebo. In general, the side effects are usually mild although a few undesired events have been reported, such as dizziness, vertigo, hypotension, bronchitis, cough, back pain, diarrhea, headache and urinary tract infection.

Contraindications
Olmesartan is contraindicated in patients who are hypersensitive to any components of this product.

Precautions
Angiotensin II receptor antagonist should be used with caution in patients with severe renal impairment (creatinine clearance 20 ml/min) and patients with severe congestive heart failure. Due to limited experience, the use of Olmesartan is not recommended in patients with hepatic impairment.

Use in pregnancy and lactation
Pregnancy Categories C (first trimester) and D (second and third trimesters). It is not known whether Olmesartan is excreted in human milk, but Olmesartan was excreted in the milk of lactating rats. Mothers must not breast-feed if they are taking Olmesartan.

Drug interactions
No significant drug interactions were reported in studies in which olmesartan was coadministered with digoxin or warfarin in healthy volunteers. The bioavailability of olmesartan was not significantly altered by the co-administration of antacids. Olmesartan medoxomil is not metabolized by the cytochrome P-450 system and has no effects on P-450 enzymes; thus, interactions with drugs that inhibit, induce, or are metabolized by those enzymes are not expected. In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists, including olmesartan medoxomil, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving olmesartan medoxomil and NSAID therapy. The antihypertensive effect of angiotensin II receptor antagonists, including olmesartan medoxomil may be attenuated by NSAIDs including selective COX-2 inhibit

Overdosage
Limited data are available related to overdosage in humans. The most likely manifestations of overdosage would be hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurs. If symptomatic hypotension occurs, initiate supportive treatment. The dialyzability of olmesartan is unknown.

Storage
Do not store above 25^0 C. Protect from light. Keep out of reach of children.

Packaging
Olpres 10 Tablet: Each box contains 3×10's tablets in blister pack.
Olpres 20 Tablet: Each box contains 3×10's tablets in blister pack.
Olpres 40 Tablet: Each box contains 3×10's tablets in blister pack.

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Manufactured by

ZISKA PHARMA

Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh

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