Olmepres Olmesartan Medoxomil Tablet

# Presentation

Olmepres 20 mg Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 20 mg.

Olmepres 40 mg Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 40 mg.

#### Description

Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation and renal reabsorption of sodium. Olmepres blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle.

### Indications

Olmepres is indicated for the treatment of hypertension, to lower blood pressure. It may be used alone or in combination with other antihypertensive agents.

### **Dosage & Administration**

The usual recommended starting dose of Olmepres is 20 mg once daily when used as mono-therapy in patients who are not volume-contracted. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmepres 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. No initial dosage adjustment is recommended for elderly patients, for patients with moderate to marked renal impairment (creatinine clearance <40 mL/min) or with moderate to marked hepatic dysfunction. For patients with possible depletion of intravascular volume (e.g., patients treated with diuretics, particularly those with impaired renal function), initiate Olmepres under close medical supervision and give consideration to use of a lower starting dose. Olmepres may be administered with or without food.

### Pediatric Hypertension (6 to 16 years of age)

Dosage must be individualized. For children who can swallow tablets, the usual recommended starting dose of Olmepres is 10 mg once daily for patients who weigh 20 to <35 kg (44 to 77 lb), or 20 mg once daily for patients who weigh  $\geq$ 35 kg. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmepres 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 weigh  $\geq$ 35 kg. Children <1 year of age must not receive Olmepres for hypertension.

#### Side Effects

The following adverse reactions occurred in placebo-controlled clinical trials at an incidence of more than 1% of patients treated with Olmepres, but also occurred at about the same or greater incidence in patients receiving placebo: back pain, bronchitis, creatine phosphokinase increased, diarrhea, headache, hematuria, hyperglycemia, hypertriglyceridemia, influenza-like symptoms, pharyngitis, rhinitis and sinusitis.

### Contraindications

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

#### Precautions

- Olmepres should be used with caution of following patients-
- 1. Hypotension in Volume- or Salt-Depleted Patients
- 2. Impaired Renal Function

### Use in Pregnancy and Lactation

Pregnancy category D

### **Nursing Mother**

It is not known whether Olmepres is excreted in human milk, but Olmepres 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.

### **Drug Interactions**

No significant drug interactions are reported in studies in which Olmepres is co-administered with digoxin or warfarin in healthy volunteers. The bioavailability of Olmepres is not significantly altered by the co-administration of antacids [AI(OH)]. Olmepres is not metabolized by the cytochrome P450 system and has no effects on P450 enzymes.

## Over Dosage

Limited data are available related to over dosage in humans. The most likely manifestations of over dosage would be hypotension and tachycardia.

### Storage Conditions

Store in a cool & dry place, away from light. Keep out of the reach of children.

### **Commercial Pack**

Olmepres 20 mg Tablet: Each box contains 3 blister packs of 10 tablets. Olmepres 40 mg Tablet: Each box contains 3 blister packs of 10 tablets.

