

DESCRIPTION

Olmesta® is a preparation of Olmesartan Medoxomil. 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. Olmesartan blocks the vasoconstrictor effects of angiotensin II is vaselectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle. Its action is, therefore, independent of the pathway for angiotensin II synthesis. An AT2 receptor is also found in many tissues, but this receptor is not known to be associated with cardiovascular homeostasis. Olmesartan has more than a 12,500-fold greater affinity to the AT1 receptor than that of AT2 receptor.

INDICATIONS

Treatment of hypertension.

DOSAGE AND ADMINISTRATION

For adults: Dosage must be individualized. The usual recommended starting dose of Olmesartan Medoxomil is 20 mg once daily when used as monotherapy in patients who are not volume-contracted. 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.

For Pediatric (6 to 16 years of age): Dosage must be individualized. For children who can swallow tablets, the usual recommended starting dose of Olmesartan Medoxomil 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 ≥35 kg. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmesartan Medoxomil 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 <35 kg.

SIDE EFFECTS

- Rash
- Vertigo
- · Abdominal pain, dyspepsia, gastroenteritis, nausea
- Tachycardia
- · Hypercholesterolemia, hyperlipemia, hyperuricemia
- · Arthralgia, arthritis, myalgia

PRECAUTIONS AND WARNINGS

In patients with an activated renin-angiotensin aldosterone system, such as volume - and/or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may be anticipated after initiation of treatment with Olmesartan. Initiate treatment under close medical supervision. As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals treated with Olmesartan Medoxomil.

USE IN PPREGNANCY AND LACTATION

Pregnancy Category D. When pregnancy is detected, discontinue Olmesartan as soon as possible. It is unknown 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.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Olmesta® 10 tablet:	Box containing 3 strips of 10 tablets each. Each tablet contains Olmesartan Medoxomil BP 10 mg.
Olmesta® 20 tablet:	Box containing 3 strips of 10 tablets each. Each tablet contains Olmesartan Medoxomil BP 20 mg.
Olmesta® 40 tablet:	Box containing 2 strips of 10 tablets each. Each tablet contains Olmesartan Medoxomil BP 40 mg.

SK+F

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