

# Duopres<sup>®</sup>

Amlodipine Besilate & Olmesartan Medoxomil

## Presentation

Duopres<sup>®</sup> 5/20: Each tablet contains Amlodipine Besilate BP 6.94mg equivalent to Amlodipine 5mg & Olmesartan Medoxomil BP 20mg.  
Duopres<sup>®</sup> 5/40: Each tablet contains Amlodipine Besilate BP 6.94mg equivalent to Amlodipine 5mg & Olmesartan Medoxomil BP 40mg.

## Description

Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Amlodipine has a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Angiotensin II formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE), is a potent vasoconstrictor, the primary vaso-active hormone of the Renin-angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Olmesartan Medoxomil blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor found in many tissues, (e.g. vascular smooth muscle, adrenal gland). In vitro binding studies indicate that Olmesartan Medoxomil is a reversible, competitive inhibitor of the AT1 receptor. Olmesartan Medoxomil does not inhibit ACE (kinase II, the enzyme that converts angiotensin I to angiotensin II and degrades bradykinin).

## Indications

Indicated for the treatment of hypertension alone or with other antihypertensive agents, to lower blood pressure. This combination drug is indicated as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals. The decision to use a combination as initial therapy should be individualized and shaped by considerations such as baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared to monotherapy. Individual blood pressure goals may vary based upon the patient's risk.

## Dosage and administration

Substitute individually titrated components for patients on Amlodipine and Olmesartan Medoxomil. This combination may also be given with increased amounts of Amlodipine, Olmesartan Medoxomil, or both, as needed.

Initial therapy: Initiate with 5/20 mg once daily for 1 to 2 weeks and titrate as needed up to a maximum of 10/40 mg once daily. Due to decreased clearance of Amlodipine among elderly patients the recommended starting dose of Amlodipine is 2.5 mg in patients  $\geq 75$  years. The lowest dose of the combination is 5/20 mg; therefore, initial therapy with this combination drug is not recommended in patients  $\geq 75$  years old.

Renal impairment: There are no studies in patients with renal impairment.

Hepatic impairment: Initial therapy is not recommended in hepatically impaired patients.

## Side-effects

The most common side effects include peripheral edema, headache, flushing and dizziness. It can also cause Intestinal problems known as sprue like enteropathy.

## Contraindications

Cannot be co-administered with Aliskiren in patients with diabetes.

## Precaution

Amlodipine and Olmesartan Medoxomil combination should be used with caution because there is a risk for-

- Hypotension in volume- or salt depleted patients
- Vasodilation in patients with severe aortic stenosis
- Increased frequency, duration or severity of angina or acute MI in patients with severe obstructive coronary artery disease

## Use in pregnancy and lactation

### Pregnancy Category D.

**Pregnancy:** Amlodipine and Olmesartan Medoxomil combination should not be used in 2nd and 3rd trimester because it can cause fetal death. When pregnancy is detected this combination should be discontinued as soon as possible.

**Nursing Mothers:** It is not known whether Olmesartan and Amlodipine are excreted in human milk. 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 interaction

The antihypertensive effect of angiotensin II receptor antagonists, including Olmesartan Medoxomil may be attenuated by NSAIDs including selective COX-2 inhibitors. Blood pressure, renal function and electrolytes should be closely monitored in patients on combination therapy and other agents that affect the RAS.

### Pediatric use

The safety and effectiveness has not been established in pediatric patients.

### Geriatric use

No overall differences in safety or effectiveness were observed between subjects 65 years of age or older and younger subjects.

## Overdose

There is no information on over dosage in humans.

## Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

## Commercial Pack

Duopres<sup>®</sup> 5/20: Each box contains 3 alu-alu blister strips of 10 tablets.

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