

Orbas Plus 20/12.5

Tablet

Olmesartan Medoxomil and Hydrochlorothiazide

Description

ORBAS PLUS 20/12.5 is a combination drug of an angiotensin II receptor antagonist (AT1 subtype), Olmesartan medoxomil, and a thiazide diuretic, Hydrochlorothiazide. Olmesartan medoxomil, a prodrug, is hydrolyzed to olmesartan during absorption from the gastrointestinal tract. It blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor. Thiazides affect the renal tubular mechanisms of electrolytes reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts.

Composition

ORBAS PLUS 20/12.5: Each film-coated tablet contains Olmesartan Medoxomil INN 20 mg and Hydrochlorothiazide BP 12.5 mg.

Indication

ORBAS PLUS 20/12.5 is indicated for the treatment of hypertension.

Dosage And Administration

Hypertension : The usual starting dose of ORBAS PLUS 20/12.5 is one tablet once daily. Depending on the blood pressure response, the dose may be titrated at intervals of 2-4 weeks to two tablets of ORBAS PLUS 20/12.5 once daily.

Patient with Renal impairment : The usual dose regimens of therapy with ORBAS PLUS 20/12.5 may be followed the patient's creatinine clearance is > 30 mL/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides. So, ORBAS PLUS 20/12.5 is not recommended.

Patient with Hepatic impairment : No dosage adjustment is necessary with hepatic impairment.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects

The common side effects are nausea, headache, dizziness, hyperuricemia, upper respiratory tract infection and urinary tract infection. Others adverse effects are chest pain, peripheral edema, abdominal pain, dyspepsia, gastroenteritis diarrhoea.

Contraindications

This combination is contraindicated in patients who are hypersensitive to any component of this product. Because of the Hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide derived drugs. It is also contraindicated in case of biliary obstruction.

Precautions

- Periodic determination of serum should be performed at appropriate interval to detect possible electrolytes imbalance like Hypokalemia and Hypochloremic alkalosis
- Hyperuricemia may occur in certain patients receiving thiazide therapy
- Impaired renal function

Use In Pregnancy And Lactation

Not recommended.

Pediatric Use

Safety and effectiveness in pediatric patients (< 18 years of age) have not been established.

Geriatric Use

Clinical studies of Olmesartan Medoxomil and Hydrochlorothiazide combination did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious.

Drug Interactions

Olmesartan Medoxomil

No significant drug interactions were reported in studies in which Olmesartan Medoxomil was co-administered with Hydrochlorothiazide, Digoxin or Warfarin in healthy volunteers.

Hydrochlorothiazide

When administered concurrently, the following drugs may interact with Thiazide :

- Alcohol, Barbiturates or Narcotics-Potentiation or orthostatic may occur
- Antidiabetic drugs (Oral agents and Insulin)-Dosage adjustment of the antidiabetic drug may be required
- Other antihypertensive drugs-Additive effect or potentiation
- Corticosteroids, ACTH
- Lithium

Overdose

Olmesartan Medoxomil

Limited data are available in regard to over dosage in humans. The most likely manifestation of over dosage would be hypotension and tachycardia. If symptomatic hypotension should occur, supportive treatment should be instituted.

Hydrochlorothiazide

The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalemia, hypochloremia, and dehydration) resulting from excessive. If, digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias.

Supply

ORBAS PLUS 20/12.5: Each box contains 3x10 tablets in blister strips.

Store in a cool & dry place, protected from light.
Keep all medicines out of reach of children.

* Further information is available on request.



Manufactured by:
The ACME Laboratories Ltd.

Dharmrai, Dhaka, Bangladesh

For Health, Vigour and Happiness

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