Only for the use of Medical Professionals

Abetis Plus®

Olmesartan Medoxomil and Hydrochlorothiazide

Description

Abetis Plus® is a combination preparation of Olmesartan Medoxomil and Hydrochlorothiazide, where Olmesartan is an Angiotensin II receptor antagonist (AT_1 subtype), and Hydrochlorothiazide is a thiazide diuretic. Olmesartan blocks the vasoconstrictor effects of Angiotensin II by selectively blocking the binding of Angiotensin II to the AT_1 receptor in vascular smooth muscle. Its action is, therefore, independent of the pathways for Angiotensin II synthesis. Hydrochlorothiazide affects the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of Hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss, and decreases in serum potassium. Co-administration of an Angiotensin II receptor antagonist (like - Olmesartan Medoxomil) tends to reverse the potassium loss associated with these diuretics (like – Hydrochlorothiazide).

Indications

Abetis Plus® is indicated for the treatment of hypertension. This combination preparation is indicated in patients whose blood pressure is not adequately controlled on Olmesartan alone. It is not indicated for initial therapy.

Dosage and administration

Dosage must be individualized. Abetis Plus® can be taken with or without food.

Adults

The usual recommended starting dose is one tablet of Abetis Plus® (20/12.5) once daily. Depending on the blood pressure response, the dose may be titrated at intervals of 2-4 weeks to two tablets of Abetis Plus® (40/25) once daily.

Elderly and renal impairment

In elderly patients the same dosage of the combination is recommended as for adults.

No dosage adjustment is necessary in patients with mild to moderate renal impairment (Creatinine clearance is ≥ 30 ml/min, < 60 ml/min). In patients with more severe renal impairment, loop diuretics are preferred to thiazides, so Abetis Plus® is not recommended.

Children and adolescents

Abetis Plus® is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

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. Thiazides appear 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.

Side-effects

Treatment with Olmesartan -hydrochlorothiazide was well tolerated, with an incidence of adverse events similar to placebo. Events generally were mild, transient and had no relationship to the dose of Olmesartan -hydrochlorothiazide, such as vertigo, coughing, back pain, rash, weakness, transient blurred vision, diarrhea, headache, and urinary tract infection.

Contraindications

This combination preparation is contraindicated in patients who are hypersensitive to the active substances, to any of the excipients or to other sulfonamide-derived substances (since Hydrochlorothiazide is a sulfonamide-derived medicinal product).

Precautions

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis and hypokalemia. Hypokalemia may develop, especially with rapid diuresis, when severe cirrhosis is present, or after prolonged therapy. As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals treated with Olmesartan.

Drug Interactions

No significant drug interactions were reported when Olmesartan was co-administered with Hydrochlorothiazide, Digoxin or Warfarin in healthy volunteers. The bioavailability of Olmesartan was not significantly altered by the co-administration of antacids [$Al(OH)_3/Mg(OH)_2$]. Olmesartan is not metabolized by the Cytochrome P450 system and has no effects on P450 enzymes; thus, interactions with drugs that inhibit, induce or are metabolized by those enzymes are not expected. Hydrochlorothiazide may cause orthostatic hypotension when administered concurrently with Alcohol, Barbiturates or Narcotics. Lithium should not generally be given with diuretics. NSAIDs can reduce the diuretic, natriuretic and antihypertensive effects of loop, potassium-sparing and thiazide diuretics.

Overdosage

Only limited information is available regarding Overdosage in humans although the most likely effect of overdosage is hypotension. If Overdosage is occurred, the patient should be carefully monitored and treatment should be symptomatic and supportive. The most common signs and symptoms of Hydrochlorothiazide overdose is electrolyte depletion i.e. – hypokalemia, hypochloremia, hyponatremia. Dehydration may also occur from excessive diuresis.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Abetis Plus® tablet: Each coated tablet contains Olmesartan Medoxomil INN 20 mg and Hydrochlorothiazide BP 12.5 mg.

Package quantities

Abetis Plus® tablet: Carton of 30 tablets in Alu-PVC blister.

® Registered Trade Mark

ACI Limited
Narayanganj, Bangladesh