Only for the use of Medical Professionals

Arbitel® Plus

Telmisartan and Hydrochlorothiazide

Description

Arbitel® Plus is a combination of Telmisartan and Hydrochlorothiazide where Telmisartan is a non-peptide angiotensin II receptor antagonist and Hydrochlorothiazide is a thiazide diuretics. Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme. Angiotensin II is the principal 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. Telmisartan blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. 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.

Indications

Arbitel® Plus is indicated for Treatment of hypertension. This combination preparation is indicated in patients whose blood pressure is not adequately controlled on Telmisartan alone. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. It is not indicated for initial therapy.

Dosage and administration

Treatment of hypertension

Initiate a patient with Arbitel® Plus 80 mg/12.5 mg once daily whose blood pressure is not adequately controlled with Telmisartan monotherapy 80 mg. Dose can be titrated up to 160 mg/25 mg after 2 to 4 weeks, if necessary. Initiate a patient with Arbitel® Plus 80 mg/12.5 mg once daily whose blood pressure is not adequately controlled by 25 mg once daily of Hydrochlorothiazide, or is controlled but who experiences hypokalemia. Dose can be titrated up to 160 mg/25 mg after 2 to 4 weeks, if necessary.

Pediatric use

Safety and effectiveness in pediatric patients have not been established.

Hepatic Insufficiency

Caution should be taken in patients with biliary obstructive disorders or hepatic insufficiency, initiate patients with biliary obstructive disorders or hepatic insufficiency at 40 mg/12.5 mg. Arbitel® Plus is not indicated for severe hepatic impairment patients.

Use in pregnancy & lactation

Pregnancy

Telmisartan is pregnancy categories C drug. When pregnancy is detected or expected, Telmisartan and Hydrochlorothiazide should be discontinued as soon as possible.

Lactation

It is not known whether Telmisartan passes into human milk. Decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother & the importance of nursing to the infant.

Side effects

The most common adverse reactions are upper respiratory tract infection, dizziness, sinusitis, diarrhea, fatigue, influenza-like symptoms, and nausea.

Contraindications

It is contraindicated in patients with known hypersensitivity of Telmisartan or Hydrochlorothiazide or any of the excipients of the products.

Precautions

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Telmisartan may potentially cause extreme low blood pressure or a decrease in kidney function. Hyperkalemia may occur in patients on ARBs, particularly in patients with advanced renal impairment, heart failure, on renal replacement therapy or on potassium supplements, potassium-sparing diuretics, potassium-containing salt substitutes or other drugs that increase potassium levels.

Drug interaction

When certain medicines are taken together, there is a possibility of developing drug interactions. With Telmisartan, drugs such as potassium supplements or potassium-sparing diuretics may cause an interaction. When Telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in through concentration (20%) where observed. NSAID use may lead to increased risk of renal impairment and loss of antihypertensive effect. Monitor renal function periodically in patients receiving Telmisartan and NSAID therapy. Increases in serum lithium concentrations and lithium toxicity have been reported with concomitant use of thiazide diuretics or angiotensin II receptor antagonists, including Telmisartan. Dosage adjustment of antidiabetic drugs may be required when co-administered with Hydrochlorothiazide.

Overdose

Telmisartan:

Limited data are available with regard to overdose in humans. The most likely manifestation of overdose with Telmisartan would be hypotension, dizziness and tachycardia. If overdose occur, supportive treatment should be given.

Hydrochlorothiazide:
The most common signs and symptoms observed in patients with a Hydrochlorothiazide overdose are those caused by electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias. The degree to which Hydrochlorothiazide is removed by hemodialysis has not been established. The oral LD50 of Hydrochlorothiazide is greater than 10 g/kg in both mice and rats.

Pharmaceutical precautions
Store in a cool (below 25°C) and dry place. Protect from light.

Presentation

Arbitel® Plus 40 tablet**:** Each coated tablet contains Telmisartan BP 40 mg & Hydrochlorothiazide BP 12.5 mg.

Arbitel® Plus 80 tablet**:** Each coated tablet contains Telmisartan BP 80 mg & Hydrochlorothiazide BP 12.5 mg.

Package quantities
Arbitel® Plus 40 tablet**:** Carton of 30 tablets in blister pack.

Arbitel® Plus 80 tablet**:** Carton of 30 tablets in blister pack.

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