Only for the use of Medical Professionals

Arbitel

Telmisartan

Description

Arbitel is a preparation of Telmisartan which is a non-peptide angiotensin II receptor antagonist. 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.

Indication

Arbitel is indicated for -

- Treatment of hypertension
- Cardiovascular risk reduction

Dosage and administration

Treatment of hypertension

In case of hypertension usually 40 mg once daily for at least 4 weeks. Increased if necessary up to maximum 80 mg once daily.

Blood pressure response is dose related over the range of 20 mg to 80 mg.

Cardiovascular risk reduction

80 mg once daily.

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

Use is pregnancy & lactation

Pregnancy

Telmisartan is pregnancy categories C drug. When pregnancy is detected or expected, telmisartan 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 side effects of telmisartan are upper respiratory infection such as common cold, flu, back pain, diarrhea and sinusitis.

Contraindications
It is contraindicated in patients with known hypersensitivity of telmisartan or a 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.

Overdose
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.

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

Presentation

Arbitel 20 tablet**:** Each coated tablet contains Telmisartan BP 20 mg.

Arbitel 40 tablet**:** Each coated tablet contains Telmisartan BP 40 mg.

Arbitel 80 tablet**:** Each coated tablet contains Telmisartan BP 80 mg.

Package quantities

Arbitel 20 tablet**:** Carton of 30 tablets in blister pack.

Arbitel 40 tablet**:** Carton of 30 tablets in blister pack.

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

ACI Limited

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