F4312B-Phl

Rx TELMISARTAN

TELSITAN-80

80 mg Film-Coated Tablet

ANGIOTENSIN II RECEPTOR BLOCKER

Formulation:
Each film-coated tablet contains:
Telmisartan BP ..... 80 mg

Pharmacology:
Telmisartan blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively blocking the binding angiotensin II to the AT_1 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. Telmisartan has much greater affinity (>3,000 fold) for the AT_1 receptor than for AT_2 receptor. Blockade of the rennin-angiotensin system with ACE inhibitors, which inhibit the biosynthesis of angiotensin II from angiotensin I, is widely used in the treatment of hypertension. Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on rennin secretion, but the resulti ng increased plasma rennin activity and angiotensin II circulating levels do not overcome the effect of Telmisartan on blood pressure.

Pharmacokinetic Properties:
Absorption
Following oral administration , peak concentrations (C_{max}) of Telmisartan are reached in 0.5-1 hour after dosing. Food slightly reduces the bioavailabil ity of Telmisartan.

Distribution
Telmisartan is highly bound to plasma proteins (>99.5%), mainly albumin and 001 acid glycoprotein. Plasma protein bindi ng is contant over the concentration range achieved with recommended doses. The volume of distribution for Telmisartan is approximately 500 liters indicating additional tissue binding.

Metabolism
Telmisartan is metabolized by conjugation to form a pharmacologically inactive acylglucuronide; the glucuronide of the parent compound is the only metabolite that has been identified in human plasma and urine. After a single dose, the glucuronide represents approximately 11% of the measured radioactivity in plasma. The cytochrome P450 isoenzymes are not involved in the metabolism of Telmisartan. Total plasma clearance of Telmisartan is >800mL I min.

Elimination
Following oral administration of Telmisartan, most of the administered dose (>97%) was eliminated unchanged in feces via biliary excretion; only minute amounts were found in the urine.

Indications:
Telmisartan is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Dosage and Administration:
The usual starting dose of Telmisartan tablet is 40 mg once a day. Blood pressure response is dose related over the range of 20 - 80 mg or as prescribed by the physician.

Contraindications:
Telmisartan is contraindicated in patients who are hypersensitive to any component of this product.

Drug Interactions:
Digoxin: It is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing Telmisartan to avoid possible over- or under-digitalization.

Warfarin: Telmisartan administered for 10 days slightly decreased the mean warfarin trough plasma concentration, this decrease is not result' in a change in International Normalized Ratio (INR).

Other Drugs: Co-administration of Telmisartan did not result in a clinically significant interaction with acetaminophen, amplodipine, glibenclamide, simvastatin, hydrochlorothiazide or ibuprofen. Telmisartan is not metabolized by the cytochrome P450 system and had no effects in vitro on cytochrome P450 enzymes, except for some inhibition of CYP2Cl 9. Telmisartan is not expected to interact with drugs that inhibit cytochrome P450 enzymes; it is also not expected to interact with drugs metabolized by cytochrome P450 enzymes, except for possible inhibition of the metabolism of drugs metabolized by CYP2C 19.

Over Dosage:
Limited data are aval lable with regard to over dosage in humans. The most likely manifestation of over dosage with Telmisartan tablets would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.
If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis .

Adverse Effects:
Adverse experiences have generall y been mild and transient in nature and have only infrequently required discontinuation of therapy. The incidence of adverse events was not dose-related and did not correlate with gender, age, or race of patients.

Autonomic Nervous System: impotence increased sweating, flushing Body as a Whole, allergy, fever, leg pain, malaise.

Cardiovascular: palpitation, dependent edema, angina pectoris tachycardia, leg edema, abnormal ECG.

CNS: insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoaesthesia.

Gastrointestinal: flatulence, constipation, gastritis, vomiting, dry mouth, hemorrhoids, gastroenteritis, enteritis, gastroesophageal reflux, toothache, non-specific gastrointestinal disorders.

Metabolic: gout, hypercholasterolemia, diabetes mellitus.

Musculoskeletal: arthritis, arthralgia, leg cramps.

Psychiatric: anxiety, depression, nervousness.

Resistance Mechanism: infection, fungal infection , abscess, otitis media.

Respiratory: asthma bronchitis rhinitis, dyspnea, epistaxis.

Skin: dermatitis, rash, eczema, pruritus.
Urinary: micturition frequency, cystitis.

Vascular: cerebrovascular disorder.

Special Senses: abnormal vision, conjunctivitis, tinnitus, earache.

Warning and Precautions:
Pregnancy
Pregnancy Categories C (First trimester) and D (Second & third trimester). Since there are no adequate or well-controlled studies in pregnant women , Telmisartan should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
It is not known whether Telmisartan is 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.

Impaired Hepatic Function
As the majority of Telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. Telmisartan tablets should be used with caution in these patients.

Impaired Renal Function
As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients whose renal function may depend on the activity of the renin-angiotensin -aldosterone system (e.g., patients with severe congestive heart failure), treatment with angiotensin-converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with tablets.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
- To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary.
- Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the importer/distributor and/or to FDA: www.fda.gov.ph.
- Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

Storage Conditions:
Store at temperature not exceeding 30°C.
Protect from light, heat and moisture.
Keep away from the reach of children.

Availability:
Alu Alu blister pack x 10's (Box of 10 and 100 Tablets)

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Manufactured by:
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