

Telcot-Trio

Composition: Telmisartan 40 mg + Amlodipine 5 mg + Hydrochlorothiazide 12.5 mg tablets

Indication: Hypertension UNCONTROLLED BY DUAL DRUG THERAPY

Mechanism of Action: Telmisartan is a nonpeptide AT1 angiotensin II receptor antagonist. It exerts antihypertensive activity by preventing angiotensin II from binding to AT1 receptors thus inhibiting the vasoconstricting and aldosterone-secreting effects of angiotensin II.

Amlodipine relaxes peripheral and coronary vascular smooth muscle. It produces coronary vasodilation by inhibiting the entry of Ca ions into the slow channels or select voltage-sensitive channels of the vascular smooth muscle and myocardium during depolarisation. It also increases myocardial oxygen delivery in patients w/ vasospastic angina.

Hydrochlorothiazide inhibits the reabsorption of Na and chloride in the distal tubules causing increased excretion of Na and water K and hydrogen ions.

Pharmacokinetic's: Onset: 1-2 hr.

Duration: Up to 24 hr.

Absorption: Rapidly absorbed from the GI tract. Food may slightly decrease the bioavailability. Absolute bioavailability: Dose-dependent (approx 42% after 40-mg dose; 58% after 160-mg dose). Time to peak plasma concentration: Approx 0.5-1 hr.

Distribution: Volume of distribution: 500 L. Plasma protein binding: >99%.

Metabolism: Undergoes conjugation w/ glucuronic acid to form inactive metabolites.

Excretion: Via faeces (97%, as unchanged drug). Terminal elimination half-life: Approx 24 hr.

Amlodipine :Absorption: Well absorbed from the GI tract. Bioavailability: Approx 60-65%. Time to peak plasma concentration: 6-12 hr.

Distribution: Volume of distribution: 21 L/kg. Plasma protein binding: Approx 98%.

Metabolism: Hepatically metabolised to inactive metabolites. Excretion: Via urine (mainly as metabolites, 10% as unchanged drug). Terminal elimination half-life: 35-50 hr.

Hydrochlorothiazide : Onset: Approx 2 hr.

Duration: 6-12 hr.

Absorption: Fairly rapid absorption from the GI tract. Food decreases rate and extent of absorption. Time to peak plasma concentration: Approx 4 hr. Bioavailability: Approx 65-70%.

Distribution: Crosses the placenta and distributed in breast milk. Volume of

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distribution: 3.6-7.8 L/kg. Plasma protein binding: Approx 40-68%. Metabolism: Not metabolised.

Excretion: Via urine as unchanged drug. Plasma half-life: Approx 5-15 hr.

Side effects:

TELMISARTAN Dizziness, fatigue, headache, sinusitis, upper resp tract infection, pharyngitis, UTI, back pain, myalgia, diarrhoea, abdominal pain, dyspepsia, nausea.

Potentially Fatal: Intermittent claudication and skin ulcer.

AMLODIPINE : Somnolence, dizziness, headache, ankle swelling, oedema, flushing, fatigue, palpitations, abdominal pain, nausea. Rarely, confusion, rash, gingival hyperplasia, muscle cramps, dyspnoea.

HYDROCHLOROTHIAZID : Electrolyte disturbances, weakness, hypotension, pancreatitis, jaundice, diarrhoea, vomiting, sialadenitis, cramping, constipation, gastric irritation, nausea, anorexia, aplastic anaemia, agranulocytosis, leukopenia, haemolytic anaemia, thrombocytopenia, anaphylactic reactions, necrotising angiitis, resp distress, photosensitivity, fever, urticaria, rash, purpura, hyperglycaemia, glycosuria, hyperuricaemia, muscle spasm, vertigo, paraesthesia, dizziness, headache, restlessness, renal failure, renal dysfunction, interstitial nephritis, erythema multiforme, exfoliative dermatitis, alopecia, transient blurred vision, xanthopsia, impotence.

Precaution:

TELMISARTAN : Volume- or salt-depleted patients including patients on prolonged diuretic therapy. Patients w/ renal artery stenosis, aortic or mitral stenosis, obstructive biliary disease. Renal and mild to moderate hepatic impairment. Lactation.

Monitoring Parameters Monitor BP, electrolytes and serum creatinine levels.

AMLODIPINE : Patients w/ cardiac failure. Hepatic and renal impairment. Elderly. Pregnancy and lactation. Patient Counselling May impair ability to drive and operate machinery. Monitoring Parameters Monitor BP and heart rate.

HYDROCHLOROTHIAZIDE Patients w/ electrolyte disturbances, history of gout, allergy or bronchial asthma, DM, parathyroid disease, hypercholesterolaemia.

May exacerbate SLE. Hepatic and mild to moderate renal impairment. Pregnancy and lactation. Monitoring Parameters Assess wt, input and output reports daily to determine fluid loss, BP, serum electrolytes, BUN, creatinine.

Dosage:

TELMISARTAN : HTN Initial: 40 mg once daily, may be adjusted to 20-80 mg once daily. CV risk reduction 80 mg once daily.

AMLODIPINE : Initially, 5 mg once daily increased to 10 mg once daily if necessary.

HYDROCHLOROTHIAZIDE : HTN Initial: 12.5 mg/day. Usual: 25-50 mg/day, up to 100 mg/day if needed.