

Eratapex Co

Olmesartan medoxomil / Amlodipine (as besylate)

CONCENTRATIONS:

Eratapex Co 20mg/5mg ,Eratapex Co 40mg/5mg , Eratapex Co 40mg/10mg.

PHARMACEUTICAL FORM:

Film Coated Tablets.

This drug is **contra-indicated during pregnancy, as it may cause injury and death to the developing foetus.**

COMPOSITION:

Eratapex Co 20 mg/5 mg film-coated tablets: White round biconvex film coated tablet. Each film-coated tablet of Eratapex Co contains 20 mg of olmesartan medoxomil and 5 mg of amlodipine (as amlodipine besylate).

Eratapex Co 40 mg/5 mg film-coated tablets: Yellow round biconvex film coated tablet scored and engraved M/A from one side and plain from the other side. Each film-coated tablet of Eratapex Co contains 40 mg of olmesartan medoxomil and 5 mg of amlodipine (as amlodipine besylate).

Eratapex Co 40 mg/10 mg film-coated tablets: Brownish pink round biconvex film coated tablet scored and engraved M/A from one side and plain from the other side. Each film-coated tablet of Eratapex Co contains 40 mg of olmesartan medoxomil and 10 mg of amlodipine (as amlodipine besylate).

INACTIVE INGREDIENTS:

Mannitol, Croscarmellose sodium, Polyvinylpyrrolidone (K25), Sodium Lauryl sulfate, Microcrystalline cellulose (PH 102), Crospovidone (XL 10), Magnesium stearate, Hydroxyl propyl methyl cellulose E5, Polyethylene glycol 6000, Titanium dioxide, Taic, Iron oxide yellow (Eratapex Co 40/5 mg) and Iron oxide red (Eratapex Co 40/10 mg).

CLINICAL PARTICULARS:

Therapeutic Indications: Treatment of essential hypertension. Eratapex Co is indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy.

DOSAGE AND ADMINISTRATION:

Adults: The recommended dose of Eratapex Co is 1 tablet per day. Eratapex Co20mg/5mg may be administered in patients whose blood pressure is not adequately controlled by 20 mg olmesartan medoxomil or 5 mg amlodipine alone. Eratapex Co 40mg/5mg may be administered in patients whose blood pressure is not adequately controlled by 20 mg olmesartan medoxomil/5 mg amlodipine. Eratapex Co40mg/10mg may be administered in patients whose blood pressure is not adequately controlled by 40 mg olmesartan medoxomil/5 mg amlodipine. A step-wise titration of the dosage of the individual components is recommended before changing to the fixed combination. When clinically appropriate, direct change from monotherapy to the fixed combination may be considered. For convenience, patients receiving olmesartan medoxomil/amlodipine from separate tablets may be switched to Eratapex Co tablets containing the same component doses. Eratapex Co can be taken with or without food.

Elderly people (age 65 years or over): No adjustment of the recommended dose is generally required for older people but increase of the dosage should take place with care. If up-titration to the maximum dose of 40 mg olmesartan medoxomil daily is required, blood pressure should be closely monitored.

Renal impairment: The maximum dose of olmesartan medoxomil in patients with mild to moderate renal impairment (creatinine clearance of 20 – 60 mL/min) is 20 mg olmesartan medoxomil once daily, owing to limited experience of higher dosages in this patient group. The use of Eratapex Co in patients with severe renal impairment (creatinine clearance < 20 mL/min) is not recommended. Monitoring of potassium levels and creatinine is advised in patients with moderate renal impairment.

Hepatic impairment: Eratapex Co should be used with caution in patients with mild to moderate hepatic impairment. In patients with moderate hepatic impairment, an initial dose of 10 mg olmesartan medoxomil once daily is recommended and the maximum dose should not exceed 20 mg once daily. Close monitoring of blood pressure and renal function is advised in hepatically-impaired patients who are already receiving diuretics and/or other antihypertensive agents. There is no experience of olmesartan medoxomil in patients with severe hepatic impairment. As with all calcium antagonists, amlodipine's half-life is prolonged in patients with impaired liver function and dosage recommendations have not been established. Eratapex Co should therefore be administered with caution in these patients. The pharmacokinetics of amlodipine have not been studied in severe hepatic impairment. Amlodipine should be initiated at the lowest dose and titrated slowly in patients with impaired liver function. Use of Eratapex Co in patients with severe hepatic impairment is contraindicated.

Paediatric population: The safety and efficacy of Eratapex Co in children and adolescents below 18 years has not been established. No data are available.

METHOD OF ADMINISTRATION:

The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water). The tablet should not be chewed and should be taken at the same time each day.

CONTRAINDICATIONS:

Hypersensitivity to the active or inactive ingredients or to dihydropyridine derivatives. Pregnancy. Severe hepatic insufficiency and biliary obstruction. Due to the component amlodipine, Eratapex Co is also contraindicated in patients with:

- Severe hypotension.
- Shock (including cardiogenic shock).
- Obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis).
- Hemodynamically unstable heart failure after acute myocardial infarction.

The concomitant use of Eratapex Co with alkalin-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60mL/min/1.7 m²).

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Dual blockade of the renin-angiotensin-aldosterone system (RAAS): There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aldiskiren increases the risk of hypotension, hyperkalemia and decreased renal function (including acute renal failure). Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aldiskiren is therefore not recommended. If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and blood pressure. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.

Patients With Hypovolemia Or Sodium Depletion: Symptomatic hypotension may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhea or vomiting, especially after the first dose. Correction of this condition prior to administration of Eratapex Co or close medical supervision at the start of the treatment is recommended.

Other Conditions With Stimulation Of The Renin-angiotensin-aldosterone System: In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with other medicinal products that affect this system, such as angiotensin II receptor antagonists, has been associated with acute hypotension, azotemia, oliguria or, rarely, acute renal failure.

Renovascular Hypertension: There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.

Renal Impairment And Kidney Transplantation: When Eratapex Co is used in patients with impaired renal function, careful monitoring of serum potassium and creatinine levels is recommended. Use of Eratapex Co is not recommended in patients with severe renal impairment (creatinine clearance < 20 mL/min). There is no experience of the administration of Eratapex Co in patients with a recent kidney transplant or in patients with end-stage renal impairment (i.e. creatinine clearance < 12 mL/min).

Hepatic Impairment: Exposure to amlodipine and olmesartan medoxomil is increased in patients with hepatic impairment. Care should be taken when Eratapex Co is administered in patients with mild to moderate hepatic impairment. In moderately impaired patients, the dose of olmesartan medoxomil should not exceed 20 mg. In patients with impaired hepatic function, amlodipine should be initiated at the lower end of the dosing range and caution should be used, both on initial treatment and when increasing the dose. Use of Eratapex Co in patients with severe hepatic impairment is contraindicated.

Hyperkalemia: As with other angiotensin II antagonists and ACE inhibitors, hyperkalemia may occur during treatment, especially in the presence of renal impairment and/or heart failure. Close monitoring of serum potassium levels in at-risk patients is recommended. Concomitant use with potassium supplements, potassium-sparing diuretics, salt substitutes containing potassium, or other medicinal products that may increase potassium levels (heparin, etc.) should be undertaken with caution and with frequent monitoring of potassium levels.

Lithium: As with other angiotensin II receptor antagonists, the concomitant use of Eratapex Co and lithium is not recommended.

Aortic or mitral valve stenosis; obstructive hypertrophic cardiomyopathy: Due to the amlodipine component of Eratapex Co, as with all other vasodilators, special caution is indicated in patients suffering from aortic or mitral valve stenosis, or obstructive hypertrophic cardiomyopathy.

Primary Aldosteronism: Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of Eratapex Co is not recommended in such patients.

Heart failure: As a consequence of the inhibition of the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Patients with heart failure should be treated with caution. In a long-term, placebo controlled study of amlodipine in patients with severe heart failure (NYHA III and IV), the reported incidence of pulmonary oedema was higher in the amlodipine group than in the placebo group. Calcium channel blockers, including amlodipine, should be used with caution in patients with congestive heart failure, as they may increase the risk of future cardiovascular events and mortality.

Spree-like Enteropathy: In very rare cases severe, chronic diarrhea with substantial weight loss has been reported in patients taking olmesartan few months to years after drug initiation, possibly caused by a localized delayed hypersensitivity reaction. Intestinal biopsies of patients often demonstrated villous atrophy. If a patient develops these symptoms during treatment with olmesartan, exclude other etiologies. Consider discontinuation of olmesartan medoxomil in cases where no other etiology is identified. In cases where symptoms disappear and spree-like enteropathy is confirmed by biopsy, treatment with olmesartan medoxomil should not be restarted.

Ethnic Differences: As with all other angiotensin II antagonists, the blood pressure lowering effect of Eratapex Co can be somewhat less in black patients than in non-black patients, possibly because of a higher prevalence of low-renin status in the black hypertensive population.

Elderly patients: In elderly patients, increase of the dosage should take place with care.

Pregnancy: Angiotensin II antagonists should not be initiated during pregnancy. Unless continued angiotensin II antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Other: As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

Potential Interactions Related To The Eratapex Co Combination: To be taken into account with concomitant use.

Other Antihypertensive Agents: The blood pressure lowering effect of Eratapex Co can be increased by concomitant use of other antihypertensive medicinal products (e.g. alpha blockers, diuretics).

Potential Interactions Related To The Olmesartan medoxomil Component Of Eratapex Co: Concomitant use not recommended.

Medicinal Products Affecting Potassium Levels: Concomitant use of potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other medicinal products that may increase serum potassium levels (e.g. heparin, ACE inhibitors) may lead to increases in serum potassium. If medicinal products which affect potassium levels are to be prescribed in combination with Eratapex Co, monitoring of serum potassium levels is recommended.

Lithium: Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors and, rarely, with angiotensin II antagonists. Therefore concomitant use of Eratapex Co and lithium is not recommended. If concomitant use of Eratapex Co and lithium proves necessary, careful monitoring of serum lithium levels is recommended.

concomitant use requiring action: Non-steroidal anti-inflammatory medicinal products (NSAIDs) including selective cox II inhibitor, acetylsalicylic acid (>3 g/day) and non selective NSAIDs: When angiotensin II antagonists are administered simultaneously with NSAIDs, the attenuation of the antihypertensive effect may occur. Furthermore concomitant use of angiotensin II antagonists and NSAIDs may increase the risk of worsening of renal function and may lead to an increase in serum potassium. Therefore monitoring of renal function at the beginning of such concomitant therapy is recommended, as well as adequate hydration of the patient.

Bile Acid Sequestering Agent Colesevelam: Concurrent administration of the bile acid sequestering agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of olmesartan and reduces 11/2. Administration of olmesartan medoxomil at least 4 hours prior to colesevelam hydrochloride decreased the drug interaction effect. Administering olmesartan medoxomil at least 4 hours before the colesevelam hydrochloride dose should be considered.

Additional Information: After treatment with antacid (aluminum magnesium hydroxide), a modest reduction in bioavailability of olmesartan was observed. Olmesartan medoxomil had no significant effect on the pharmacokinetics or pharmacodynamics of warfarin or the pharmacokinetics of digoxin. Coadministration of olmesartan medoxomil with pravastatin had no clinically relevant effects on the pharmacokinetics of either component in healthy subjects. Olmesartan had no clinically relevant inhibitory effects on human cytochrome P450 enzymes 1A1/2, 2A6, 2C8/9, 2C19, 2D6, 2E1 and 3A4 in vitro, and had no or minimal inducing effects on rat cytochrome P450 activities. No clinically relevant interactions between olmesartan and medicinal products metabolised by the above cytochrome P450 enzymes are expected.

Potential Interactions Related To Amlodipine: Effects of other medicinal products on amlodipine.

CYP3A4 Inhibitors: Concomitant use of amlodipine with strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides like erythromycin or clarithromycin, verapamil or diltiazem) may give rise to significant increase in amlodipine exposure. The clinical translation of these PK variations may be more pronounced in older people. Clinical monitoring and dose adjustment may thus be required.

CYP3A4 Inducers: There is no data available regarding the effect of CYP3A4 inducers on amlodipine. The concomitant use of CYP3A4 inducers (i.e. rifampicin, hypericumperforatum) may give a lower plasma concentration of amlodipine. Amlodipine should be used with caution together with CYP3A4 inducers. Administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects. Dantrolene (infusion). In animals, lethal ventricular fibrillation and cardiovascular collapse are observed in association with hyperkalemia after administration of verapamil and intravenous dantrolene. Due to risk of hyperkalemia, it is recommended that the co-administration of calcium channel blockers such as amlodipine be avoided in patients susceptible to malignant hyperthermia and in the management of malignant hyperthermia.

Effects Of Amlodipine On Other Medicinal Products: The blood pressure lowering effects of amlodipine adds to the blood pressure-lowering effects of other antihypertensive agents. In clinical interaction studies, amlodipine did not affect the pharmacokinetics of atrovastatin, digoxin, warfarin or cyclosporine.

Simvastatin: Co-administration of multiple doses of 10 mg of amlodipine with 80 mg simvastatin resulted in a 77% increase in exposure to simvastatin compared to simvastatin alone. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.

FERTILITY, PREGNANCY AND LACTATION:

PREGNANCY:

This drug is contra-indicated during pregnancy, as it may cause injury and death to the developing foetus. Unless continued angiotensin II antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Amlodipine (active ingredient of Eratapex Co): Data on a limited number of exposed pregnancies do not indicate that amlodipine or other calcium receptor antagonists have a harmful effect on the health of the fetus. However, there may be a risk of prolonged delivery. As a consequence, Eratapex Co is not recommended during the first trimester of pregnancy and is contraindicated during the second and third trimesters of pregnancy.

LACTATION:

Olmesartan is excreted into the milk of lactating rats. However, it is not known whether olmesartan passes into human milk. It is not known whether amlodipine is excreted in breast milk. Similar calcium channel blockers of the dihydropyridine type are excreted in breast milk. Because no information is available regarding the use of olmesartan and amlodipine during breast-feeding, Eratapex Co is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

FERTILITY:

Reversible biochemical changes in the head of spermatozoa have been reported in some patients treated by calcium channel blockers. Clinical data are insufficient regarding the potential effect of amlodipine on fertility. In one rat study, adverse effects were found on male fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Eratapex Co can have minor or moderate influence on the ability to drive and use machines. Dizziness, headache, nausea or fatigue may occasionally occur in patients taking antihypertensive therapy, which may impair the ability to react. Caution is recommended especially at the start of treatment.

UNDESIRABLE EFFECTS:

The most commonly reported adverse reactions during treatment with Olmesartan / Medoxomil are peripheral oedema, headache and dizziness. The following treatments have been used in order to classify the occurrence of adverse reactions:

- Severe (≥1/10),
- Common (≥1/100 to <1/10),
- Uncommon (≥1/1,000 to <1/100),
- Rare (≥1/10,000 to <1/1,000),
- Very rare (<1/10,000), not known (cannot be estimated from the available data).

MedDRA System Organ Class	Adverse Reactions	Frequency Olmesartan/Amlodipine combination	Olmesartan	Amlodipine
Blood and lymphatic system disorders	Leukocytopenia		Uncommon	Very rare
	Thrombocytopenia		Uncommon	Very rare
Immune system disorders	Allergic reaction (drug hypersensitivity)	Rare	Uncommon	Very rare
	Idiosyncratic reaction		Uncommon	Very rare
Metabolism and nutrition disorders	Hypoglycemia			Very rare
	Hyperkalemia	Uncommon	Rare	
	Hypertriglyceridemia	Common	Common	
	Hypertigremia	Common	Common	
	Hyperuricemia	Common	Common	
Psychiatric disorders	Confusion			Rare
	Depression		Uncommon	Uncommon
	Insomnia		Uncommon	Uncommon
	Irritability		Uncommon	Uncommon
	Lbido decreased	Uncommon		
	Mood changes (including anxiety)		Uncommon	
	Dizziness	Common	Common	Uncommon
	Dysgeusia		Uncommon	Uncommon
	Headache	Common	Common	Common (especially at the beginning of treatment)
	Hyperphonia			Very rare
Nervous system disorders	Hypoaesthesia	Uncommon	Uncommon	Uncommon
	Lethargy	Uncommon		Uncommon
	Paraesthesia	Uncommon		Uncommon
	Peripheral neuropathy			Very rare
	Postural dizziness	Uncommon		
	Sleep disorder		Uncommon	Uncommon
	Somnolence		Uncommon	Uncommon
	Syncope	Rare	Uncommon	Uncommon
	Tremor		Uncommon	Uncommon
	Visual disturbance (including diplopia)		Uncommon	Uncommon
Eye disorders	Myopia		Uncommon	Uncommon
	Ear and labyrinth disorders	Uncommon	Uncommon	
Cardiac disorders	Angina pectoris	Uncommon	Uncommon (incl. aggravation of angina pectoris)	Uncommon
	Arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation)			Very rare
Vascular disorders	Myocardial infarction			Very rare
	Palpitations	Uncommon	Uncommon	Uncommon
	Tachycardia	Uncommon	Uncommon	
	Hypotension	Uncommon	Rare	Uncommon
	Orthostatic hypotension	Uncommon		
	Flushing	Rare		Common
	Vasodilation			Common
	Bronchitis		Common	Uncommon
	Cough	Uncommon	Common	Very rare
	Dyspnea	Uncommon	Uncommon	Uncommon
Respiratory, thoracic and mediastinal disorders	Pharyngitis		Common	Uncommon
	Rhinitis		Common	Common
	Abdominal pain		Common	Common
	Altered bowel habits (including diarrhea and constipation)			Uncommon
	Constipation	Uncommon		Uncommon
	Diarrhea	Uncommon	Common	
	Fly mouth	Uncommon		Uncommon
	Dyspepsia	Uncommon	Common	Uncommon
	Gastritis			Very rare
	Gastroenteritis		Common	
Gastrointestinal disorders	Gingival hyperplasia		Very rare	Uncommon
	Rosacea	Uncommon	Common	Uncommon
	Parosmia			Very rare
	Upper abdominal pain	Uncommon		Uncommon
	Vomiting	Uncommon	Uncommon	Uncommon
	Spur-like enteropathy (see section 4.4)	Very rare		
	Hepatic enzymes increased	Common	Very rare (mostly consistent with cholestasis)	
	Hepatitis		Very rare	Uncommon
	Jaundice		Very rare	Uncommon
	Anorexia			Uncommon
Skin and subcutaneous tissue disorders	Angioneurotic oedema	Rare	Very rare	
	Allergic dermatitis	Uncommon		Uncommon
	Cyrtoma multiforme		Very rare	Uncommon
	Eczematema	Uncommon		Uncommon
	Exfoliative dermatitis		Very rare	Uncommon
	Hyperhidrosis		Uncommon	Uncommon
	Photosensitivity		Very rare	Uncommon
	Pruritus	Uncommon		Uncommon
	Purpura		Uncommon	Uncommon
	Quincke's Oedema		Very rare	Uncommon
Hepato-biliary disorders	Rash	Uncommon	Uncommon	Uncommon
	Skin discoloration		Uncommon	Uncommon
	Stevens-Johnson syndrome		Very rare	Uncommon
	Urticaria	Rare	Uncommon	Very rare
	Ankle swelling		Common	Uncommon
	Arthralgia		Common	Uncommon
	Arthritis	Common		Uncommon
	Back pain	Uncommon	Common	Uncommon
	Muscle spasms	Rare	Uncommon	Uncommon
	Myalgia	Uncommon		Uncommon
Renal and urinary disorders	Pain in extremity	Uncommon		Uncommon
	Skeletal pain		Common	
	Acute renal failure		Rare	Uncommon
	Hematuria		Common	Uncommon
	Increased urinary frequency		Uncommon	Uncommon
	Micturition disorder		Uncommon	Uncommon
	Nocturia			Uncommon
	Poliakuria	Uncommon		
	Renal insufficiency		Rare	Uncommon
	Urinary tract infection		Common	Uncommon
Reproductive system and breast disorders	Erectile dysfunction/impotence	Uncommon		Uncommon
	Gynecomastia			Uncommon
General disorders and administration site conditions	Asthenia	Uncommon	Uncommon	Uncommon
	Chest pain		Common	Uncommon
	Face oedema	Rare	Common	Uncommon
	Edema	Common	Common	Common
	Influenza-like symptoms		Common	
	Lethargy		Rare	Uncommon
	Malaise		Uncommon	Uncommon
	Oedema	Common		Common
	Pain	Common	Common	Uncommon
	Peripheral oedema	Common	Common	
Investigations	Pitting oedema	Common		
	Blood creatinine increased	Uncommon	Rare	
	Blood creatinine phosphokinase increased		Common	
	Blood potassium decreased	Uncommon		
	Blood urea increased		Common	
	Blood uric acid increased	Uncommon		
	Gamma glutamyl transferase increased	Uncommon		
	Weight decrease			Uncommon
	Weight increase			Uncommon

Single cases of rhabdomyolysis have been reported in temporal association with the intake of angiotensin II receptor blockers. Single cases of extrapyramidal syndrome have been reported in patients treated with amlodipine.

OVERDOSE:

Symptoms: There is no experience of overdose with Olmesartan medoxomil / Amlodipine as besylate fixed dose combination. The most likely effects of Olmesartan Medoxomil overdose are hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurred. Amlodipine overdosage can be expected to lead to excessive peripheral vasodilatation with marked hypotension and possibly a reflex tachycardia. Marked and potentially prolonged systemic hypotension up to and including shock with fatal outcome has been reported.

Treatment: If intake is recent, gastric lavage may be considered. In healthy subjects, the administration of activated charcoal immediately or up to 2 hours after ingestion of amlodipine has been shown to reduce substantially the absorption of amlodipine. Clinically significant hypotension due to an overdose of Eratapex Co requires active support of the cardiovascular system, including close monitoring of heart and lung function, elevation of the extremities, and attention to circulating fluid volume and urine output. A vasconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit. The daily salt balance of olmesartan is unknown.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic Properties: Pharmacotherapeutic group: Angiotensin II antagonists and calcium channel blockers.