Camlosart™

Amlodipine + Olmesartan Medoxomil

PRESENTATION
Camlosart™ 5/20 tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil INN 20 mg.
Camlosart™ 5/40 tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil INN 40 mg.

DESCRIPTION
This product is a combination of two antihypertensive drugs: a dihydropyridine calcium antagonist, Amlodipine and an angiotensin II receptor blocker, Olmesartan Medoxomil. The Amlodipine component inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle and the Olmesartan Medoxomil component blocks the vasoconstrictor effects of angiotensin II.

INDICATIONS
Camlosart™ is indicated for the treatment of hypertension, alone or with other antihypertensive agents.
Camlosart™ may also be used as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals.

DOSAGE & ADMINISTRATION
Initial Therapy
The usual starting dose of **Camlosart**™ is one tablet (5/20 mg) once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum dose of 10/40 mg once daily as needed to control blood pressure. **Camlosart**™ may be taken with or without food. **Camlosart**™ may be administered with other antihypertensive agents.
Initial therapy with this combination product is not recommended in patients > 75 years old or with hepatic impairment.
Replacement Therapy
Camlosart™ may be substituted for its individually titrated components. When substituting for individual components, the dose of one or both of the components can be increased if blood pressure control has not been satisfactory.
Add-on Therapy
Camlosart™ may be used to provide additional blood pressure lowering for patients not adequately controlled with Amlodipine (or another dihydropyridine Calcium Channel Blocker) alone or with Olmesartan Medoxomil (or another angiotensin II receptor blocker) alone.

CONTRAINDICATION
Hypersensitivity to any of the component of this combination product.

SIDE EFFECTS
The reported adverse reactions were generally mild and seldom led to discontinuation of treatment. The most common side effects include edema, dizziness, flushing, palpitation. Other side effects may include vomiting, diarrhoea, rhabdomyolysis, alopecia, pruritus, urticaria etc.

USE IN SPECIAL POPULATION
Pregnancy: When pregnancy is detected, discontinue this combination product as soon as possible. When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.
Nursing Mothers: 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.
Children: The safety and effectiveness in pediatric patients have not been established.

PRECAUTION
Fetal/Neonatal morbidity and mortality: When pregnancy is detected, this combination drug should be discontinued as soon as possible. Hypotension in volume- or salt-depleted patients: Symptomatic hypotension may occur after initiation of therapy. Vasodilation: Exercise caution, when administering this combination, particularly in patients with severe aortic stenosis. Patients with Severe Obstructive Coronary Artery Disease: Patients may develop increased frequency, duration, or severity of angina or acute MI on starting Calcium Channel Blocker therapy or at the time of dosage increase. Patients with Congestive Heart Failure: Calcium Channel Blocker should be used with caution. Patients with Impaired Renal Function / Hepatic Impairment: Should be used with caution.

DRUG INTERACTION
The pharmacokinetics of Amlodipine and Olmesartan Medoxomil are not altered when the drugs are co-administered. No drug interaction studies have been conducted with Amlodipine and Olmesartan combination tablet and other drugs, although studies have been conducted with the individual Amlodipine and Olmesartan Medoxomil components and no significant drug interactions have been observed.

STORAGE CONDITION
Store in a cool and dry place, protect from light and moisture. Store at 25°C. Keep out of the reach of children.

HOW SUPPLIED
Camlosart™ 5/20 tablet: Each box contains 30 tablets in blister pack.
Camlosart™ 5/40 tablet: Each box contains 20 tablets in blister pack.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH
TM - Trade Mark