OLMEDIP

AMLODIPIN BESILATE BP + OLMESARTAN MEDOXIMIL BP

Compositions:
Olmedip-5/20 Tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil BP 20 mg. Olmedip-5/40 Tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Olmesartan Medoxomil BP 40 mg.

Pharmacology:
Olmedip is a combination product containing Amlodipine and Olmesartan. Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle & cardiac muscle. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance & a reduction in blood pressure. Olmesartan is an angiotensin II receptor blocker that acts on AT1 subtype. By blocking the action of angiotensin II, Olmesartan dilates blood vessels and reduces blood pressure without affecting pulse rate.

Dosage And Administration:
Initial Therapy: The usual starting dose of Olmedip 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. Olmedip may be taken with or without food. Olmedip 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: Olmedip 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: Olmedip 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.

Contraindications:
Hypersensitivity to any of the component of this combination product.

Warning And Precaution:
When pregnancy is detected, this combination drug should be discontinued as soon as possible. Symptomatic hypotension may occur after initiation of therapy. Exercise caution, during administering this combination, particularly in patients with severe aortic stenosis, patients with Severe Obstructive Coronary Artery Disease, patients with Congestive Heart Failure, patients with Impaired Renal Function / Hepatic Impairment.

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 Pregnancy and Lactation:
Pregnancy: Pregnancy category D. 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.

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.

Overdosage:
There is no information on over dosage in humans

Storage:
Store in a cool and dry place, protect from light and moisture. Store at 25 oC. Keep out of the reach of children.

Packing:
Olmedip-5/20 tablet: Each box contains 5 x 10's tablet in Alu-Alu blister pack. Olmedip-5/40 tablet: Each box contains 3 x 10's tablet in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.