# Camoval®

Amlodipine + Valsartan Calcium Channel Blocker + Angiotensin Receptor Blocker

#### PRESENTATION

**Camoval<sup>®</sup> 5/80** tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Valsartan USP 80 mg.

**Camoval**<sup>®</sup> **5/160** tablet: Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Valsartan USP 160 mg.

# USES

For the treatment of hypertension.

# **DOSAGE & ADMINISTRATION**

Amlodipine is an effective treatment of hypertension in once daily doses of 2.5 mg - 10 mg while Valsartan is effective in doses of 80 mg - 320 mg. In clinical trials with Amlodipine and Valsartan, using amlodipine doses of 5 mg - 10 mg and Valsartan doses of 160 mg - 320 mg, the antihypertensive effects increased with increasing doses. The majority of the antihypertensive effect is attained within 2 weeks after initiation of therapy or a change in dose. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of 10/320 mg once daily as needed to control blood pressure.

**Camoval**<sup>®</sup> may be administered with or without food. **Camoval**<sup>®</sup> may be administered with other antihypertensive agents. A patient whose blood pressure is not adequately controlled with Amlodipine alone or with Valsartan alone may be switched to this combination therapy.

*Elderly patients:* Because of decreased clearance of Amlodipine, therapy should usually be initiated at 2.5 mg.

*Renal Impairment:* No initial dosage adjustment is required for patients with mild or moderate renal impairment. Titrate slowly in patients with severe renal impairment.

*Hepatic Impairment:* No initial dosage adjustment is required for patients with mild or moderate liver insufficiency. Titrate slowly in patients with hepatic impairment.

#### CONTRAINDICATION

This combination product is contraindicated in patients who are hypersensitive to any components of this product.

# SIDE EFFECTS

Generally been mild and transient in nature. The most common side effects include peripheral edema, nasal congestion, sore throat and discomfort when swallowing, upper respiratory tract infection, dizziness etc.

#### PRECAUTION

Avoid fetal or neonatal exposure, assess for hypotension, warn patients with severe obstructive coronary artery disease about the risk of myocardial infarction or increased angina, titrate slowly in patients with impaired hepatic or severely impaired renal function.

# USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy Category D.

*Nursing Mothers:* It is not known whether Amlodipine or Valsartan 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.

# USE IN CHILDREN

Safety and effectiveness in paediatric patients have not been established.

# DRUG INTERACTIONS

No drug interaction studies have been conducted with Amlodipine and Valsartan combination, although studies have been conducted with the individual components.

#### **STORAGE CONDITION**

Store in a cool and dry place, protect from light and moisture. Keep out of the reach of children.

#### HOW SUPPLIED

**Camoval<sup>®</sup> 5/80** tablet: Each box contains 30 tablets in alu-alu blister pack. **Camoval<sup>®</sup> 5/160** tablet: Each box contains 20 tablets in alu-alu blister pack.

Manufactured by:



<sup>®</sup> Registered Trade Mark