For the use of Registered Medical Practitioner or a Hospital or a Laboratory.

AMTAS

(Amlodipine Besylate Tablets USP 5/10 mg)

Amtas is a slow calcium channel blocker of dihydropyridine class. Amtas is indicated as therapy for mild to moderate hypertension and in ischaemic heart disease. Amtas has 24 hours duration of action permitting once a day dosage.

Clinical pharmacology
Amtas selectively inhibits transmembrane influx of calcium ions, with greater selectivity for vascular smooth muscle than for myocardial tissue. This results in vasodilatation and in reduction of blood pressure. The decrease in myocardial oxygen requirement along with coronary vasodilation accounts for beneficial effects in myocardial ischaemia. Amtas has gradual and sustained onset of action and blood pressure reduction is not associated with reflux tachycardia. Amtas has no significant effect on sinus node function or cardiac conduction. Amtas is slowly and completely absorbed after oral administration with peak serum concentrations occuring after 6 to 12 hours. Oral bioavailability is 64% which is not influenced by food. Amtas has prolonged terminal elimination half-life of 35 to 50 hours and steady state concentrations are achieved after 7 to 8 days of administration. Amtas is extensively metabolized. Metabolites are mostly excreted in urine with less than 10% of a dose as unchanged drug. Amtas is 97% protein bound.

Indications
1. Therapy for mild to moderate hypertension.
2. Angina pectoris:
 a) chronic stable angina
 b) vasospastic (prinzmetal's or variant) angina.

Dosage and administration
Hypertension: Initially 5 mg once daily, increased to 10 mg once daily, if required.
Angina pectoris: 5 to10 mg is given once daily. Small fragile or elderly individuals, or patients with hepatic insufficiency may be started on 2.5 mg once daily. This dosage may be used with other antihypertensive therapy.

Contraindications, Caution and Precautions
Amtas is contraindicated in patients with known hypersensitivity to dihydropyridine derivatives. In elderly patients and those with liver disease, elimination of amlodipine is significantly reduced and half life is prolonged. In such patients Amtas should be given with caution with appropriate dose reduction. All calcium channel blockers including Amtas should be used with caution in patients with heart failure. No dose adjustment is required in patients with renal impairment. Safety and efficacy of Amtas during pregnancy and lactation is not established.

Drug interactions
No significant drug interactions have been reported.

Side effects
Amtas is well tolerated. Usual side effects reported are headache, dizziness, flushing, palpitations, peripheral oedema, fatigue, somnolence and abdominal pain. Less frequently reported side effects are muscle cramps, dyspnoea, dyspepsia, gingival hyperplasia, pruritis and rash.

Overdosage
In case of overdosage, the prominent feature is hypotension. Gastric lavage as well as symptomatic and supportive measures to maintain blood pressure are indicated. Haemodialysis is not of value in removing circulating amlodipine as it is highly protein bound.

Storage:
Store in cool & dark place.

Presentation:
Amtas- 5 and 10 tablets are available in strips of 7 tablets and in HDPE containers of 100 and 1000 tablets.

Manufactured by:

INTAS

INTAS PHARMACEUTICALS LTD.
Selaqui, Dehradun-248 197. INDIA
80 1084 0 8610170

	Checked by				Approved by
Department	PMQC	RA	Packing Dev.	Q.A.	Head Q.A.
Signature					
Date					

Product Name : AMTAS
Size : 70 x 210 (mm)
Folding Size : 70 x 30 (mm)
No. of Col. : 1
Date : 06/11/15

File name : 8610170-AMTAS-PIL
Col. Shade No. : Pantone Black