AMDIPINE Tablets

(Amlodipine Besylate Tablets USP)

COMPOSITION:
Each film coated tablet contains:
Amlodipine Besylate USP equivalent to Amlodipine ... 5mg & 10mg. [USP Specs.]

DESCRIPTION:
AMDIPINE tablets (Amlodipine Besylate) is dihydropyridine calcium antagonist. It inhibits the transmembrane influx of calcium ions into the cardiac muscle and smooth muscle.

PHARMACOKINETIC PROPERTIES:
Absorption & distribution:
After oral administration of therapeutic doses, Amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. The volume of distribution is approximately 21 l/kg. *In vitro* studies have shown that approximately 97.5% of circulating Amlodipine is bound to plasma proteins. The bioavailability of Amlodipine is not affected by food intake.

Biotransformation/Elimination:
The terminal plasma elimination half-life is about 35-50 hours and is consistent with once daily dosing. Amlodipine is extensively metabolized by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine.

Hepatic impairment:
Patients with hepatic insufficiency have decreased clearance of Amlodipine resulting in a longer half-life and an increase in AUC of approximately 40-60%.

Elderly population:
The time to reach peak plasma concentrations of Amlodipine is similar in elderly and younger subjects. Amlodipine clearance tends to be decreased with resulting increases in AUC and elimination half-life in elderly patients. Increases in AUC and elimination half-life in patients with congestive heart failure were as expected for the patient age group studied.

Paediatric population:
In children 6 to 12 years and in adolescents 13-17 years of age the typical oral clearance (CL/F) was 22.5 and 27.4 L/hr respectively in males and 16.4 and 21.3 L/hr respectively in females. Large variability in exposure between individuals was observed. Data reported in children below 6 years is limited.

INDICATIONS:
AMDIPINE is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of **AMDIPINE**; which has been used in combination with thiazide diuretic, b-adrenoceptor blocking agent or an angiotensin converting enzyme inhibitor.
AMDIPINE is indicated for the first line treatment of myocardial ischemia whether due to fixed obstruction (stable angina) and/or vasospasm/ vasoconstriction (prinzmetal's or variant angina) of coronary vasculature.
AMDIPINE may be used when the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/ vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of b-blockers.

DOSAGE AND ADMINISTRATION:
Adults: Usual initial dose is 5mg once daily, which may be increased to a maximum daily dose of 10mg depending on the individual patient's response. No dose adjustment of Amlodipine is required upon concomitant administration of thiazide diuretics, b-blockers and ACE angiotensin, ACE converting, ACE enzyme inhibitors (ACE inhibitors).

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ADVERSE REACTIONS:
Dizziness, flushing, headache, hypotension, edema, palpitation, nausea and other gastro-intestinal disturbances, increased micturition frequency, lethargy, eye pain, and mental depression may also occur.

CONTRA-INDICATIONS:
Contra-indicated in patients with hypersensitivity to dihydropyridine derivatives, amlodipine or to any of the excipients, severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle (e.g., high grade aortic stenosis) & haemodynamically unstable heart failure after acute myocardial infarction.

PRECAUTIONS:
Should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor and in patients with impaired hepatic function.

DRUG INTERACTIONS:
Amlodipine may enhance the antihypertensive effects of β-blockers. Amlodipine may modify insulin and glucose response and therefore diabetic patients may need to adjust their antidiabetic treatment when receiving Amlodipine. It is extensively metabolized in liver by the cytochrome p450 enzyme system, and interaction may occur with other drugs such as quinidine, sharing the same metabolic pathway and with enzyme inducers such as phenytoin and rifampicin and enzyme inhibitor such as cimetidine.

INSTRUCTIONS:
Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:
AMDIPINE (Amlodipine) tablets 5mg and 10mg are available in pack of 3x10's.

ایمڈیپین گولیاں

(ایملوڈیپین بیسائیلیٹ)

اجزاءترکیب:
ایمڈیپین کی ہر فلم کوٹڈ گولی میں ایملوڈیپین ۵ ملی گرام یا ۱۰ ملی گرام بحیثیت ایملوڈیپین بیسائیلیٹ شامل ہے۔

فوائد: ایمڈیپین گولیاں بلندفشارِخون میں فائدہ مند ہیں۔

خوراک اور طریقہ استعمال:
بالغ افراد: ابتدائی خوراک ۵ ملی گرام روزانہ ہے جو کہ زیادہ سے زیادہ ۱۰ ملی گرام روزانہ تک بڑھائی جاسکتی ہے۔

مضر اثرات: کبھی کبھار مندرجہ ذیل مضر اثرات دیکھنے میں آتے ہیں۔ سر درد، قے کا محسوس ہونا، پیشاب کا بار بار آنا اور افسردگی وغیرہ۔

مانع علامات: Dihydropyridines اور دوا کے کسی جُز سے حساسیت سے حساس مریض دوا کے استعمال سے گریز کریں۔

خوراک: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: ایمڈیپین گولیاں ۵ ملی گرام اور ۱۰ ملی گرام گولیاں ۳۰ گولیوں کے بلسٹر پیک میں دستیاب ہیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.
Rev: 12-18/4