NUDIPIN 10

Nifedipine Tablets 10 mg

DESCRIPTION

Nudipin 10 tablets are uncoated, yellow in color, circular beveled edged with a break line on one side and plain surface on the other side, packed in blister packings.

COMPOSITION

Each Uncoated Tablet Contains: Nifedipine BP 10 mg

MODE OF ACTION

Nifedipine is antianginal/antihypertensive drug belonging to a class of pharmacological agent known as the calcium channel blockers. Nifedipine is 3,5-pyridinedicarboxylic acid 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-, dimethyl ester, $C_{17}H_{18}N_2O_6$.

Nifedipine is a calcium ion influx inhibitor (slow channel blocker or calcium ion antagonist) and inhibits the trans-membrane influx of calcium ions into cardiac muscle and smooth muscle. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Nifedipine selectively inhibits calcium ion influx across the cell membrane of cardiac muscle and vascular smooth muscle without altering serum calcium concentrations.

SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS

Nudipin 10 is rapidly and fully absorbed after oral administration. The drug is detectable in serum 10 minutes after oral administration, and peak blood levels occur in approximately 30 minutes. Bioavailability is proportional to dose from 10 to 30mg; half-life does not change significantly with dose.

Nudipin 10 is extensively converted to inactive metabolites and approximately 80% of nifedipine and metabolites are eliminated via the kidneys. The half-life of nifedipine in plasma is approximately 2 hours. Since hepatic biotransformation is the predominant route for the disposition of nifedipine, the pharmacokinetics may be altered in patients with chronic liver disease. Patients with hepatic impairment (liver cirrhosis) have a longer disposition half-life and higher bioavailability of nifedipine than healthy volunteers. The degree of serum protein binding of nifedipine is also high (92-98%). Protein binding may be greatly reduced in patients with renal or hepatic impairment.

INDICATIONS

Nudipin 10 is indicated for the management of vasospastic angina pectoris including Prinzmetal's angina and variant angina, chronic stable angina (angina of effort). Nudipin 10 is also used in the treatment of hypertension and hypertensive crisis. Treatment of coronary heart disease.

ADVERSE REACTIONS/SIDE EFFECTS

Adverse effects were frequent but generally not serious and rarely required discontinuation of therapy or dosage adjustment. Most were expected consequences of the vasodilator effect of nifedipine.

Central nervous system : lightheadedness or dizziness, nervousness, mood changes

Systemic : headache, fatigue, flushing, heat sensation, weakness

Gastro intestinal: constipation, nausea, heartburn

Cardiovascular: peripheral edema, palpitation

Musculoskeletal: muscle cramp, tremor

Respiratory: nasal congestion, dyspnoea, cough, wheezing

PRECAUTIONS/WARNINGS

Nudipin 10 is not a beta-blocker and therefore gives no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be gradual reduction of the dose of beta-blocker, preferably over 8-10 days. Nudipin 10 may be used in combination with beta-blocker drugs and other antihypertensive agents but the possibility of an additive effect resulting in postural hypotension should be borne in mind. Nudipin 10 will not prevent possible rebound effects after cessation of other antihypertensive therapy. Nudipin 10 should be used with caution in patients whose cardiac reserve is poor. Deterioration of heart failure has occasionally been observed with nifedipine. At doses higher than those recommended, there is some concern about increased mortality and morbidity in the treatment of ischaemic heart disease, in particular after myocardial infarction. Treatment with short-acting nifedipine may induce an exaggerated fall in blood pressure and reflex tachycardia which can cause cardiovascular complications such as myocardial and cerebrovascular ischaemia. Caution should be exercised in patients with severe hypotension. Ischaemic pain has been reported in a small proportion of patients within 30 to 60 minutes of the introduction of Nudipin 10 therapy. Although a 'steal' effect has not been demonstrated, patients experiencing this effect should discontinue Nudipin 10 . The use of Nudipin 10 in diabetic patients may require adjustment of their control. In dialysis patients with malignant hypertension and hypovolaemia, a marked decrease in blood pressure can occur. Whilst nifedipine is contra-indicated in pregnancy, particular care must be exercised when administering nifedipine in combination with i.v. magnesium sulphate to pregnant women. Several well-documented studies have described profound hypotension, myocardial infarction and death when immediate release nifedipine capsules are used sublingually for acute reduction of blood pressure.

DRUG INTERACTIONS

Beta adrenergic blocking agents :

There have been occasional literature reports suggesting concomitant administration with beta blockers may increase the likelihood of congestive heart failure, severe hypotension and angina.

Long acting nitrates :

Nudipin 10 may be safely co-administered with nitrates, but there have been uncontrolled studies to evaluate the effectiveness.

Digitalis :

It is recommended that digoxin levels be monitored when initiating, adjusting and discontinuing nifedipine to avoid possible over- or underdigitalization.

Coumarin anticoagulant :

There have been rare reports of increase in prothrombin time in patients taking coumarin

and nifedipine concomitantly. However, the relationship is uncertain.

Cimetidine :

A study has shown a significant increase in nifedipine plasma level after a course of cimetidine and nifedipine. Ranitidine produced smaller, non-significant increase. If nifedipine therapy is initiated in patients who are on cimetidine, cautious titration is advised.

Phenytoin :

Monitor clinical response to nifedipine as its bioavailability is reduced due to the cytochrome P450 3A4 system induction by phenytoin. An increase in nifedipine dose may be necessary.

Cisapride :

Blood pressure should be monitored and a decrease in the dosage of nifedipine may be necessary as simultaneous administration with cisapride may lead to an increased plasma concentration of nifedipine.

Rifampicin :

Rifampicin significantly induces the cytochrome P450 3A4, thus the bioavailability of nifedipine is drastically reduced. Concomitant administration of nifedipine and rifampicin is contraindicated.

Quinidine :

The dose of nifedipine may require reduction when administered with quinidine as distinct increases in plasma concentration of nifedipine have been observed with the co-administration of these two drugs.

Quimupristin/Dalfopristin :

The dose of nifedipine may require reduction when administered with quimupristin/dalfopristin as distinct increases in plasma concentration of nifedipine have been observed with the co-administration of these two drugs.

USE IN PREGNANCY

Nudipin 10 is contra-indicated in women capable of child-bearing. The safety of Nudipin 10 for use in human pregnancy has not been established. Evaluation of experimental animal studies has shown reproductive toxicity consisting of embryotoxicity and teratogenic effects at maternally toxic doses. Nudipin 10 is contra-indicated in nursing mothers as NIFEDIPINE may be present in breast milk.

CONTRAINDICATIONS

Nudipin 10 is contraindicated in pregnancy and lactation and patients with known hypersensitivity to nifedipine. It is also contraindicated in unstable angina, cardiovascular shock and within a period of one month after myocardial infarction. Other contraindications include, low blood pressure and with concomitant use of rifampicin.

RECOMMENDED DOSAGE AND ADMINISTRATION

The dosage of Nudipin 10 needed to suppress angina and that can be tolerated by the patient must be established by titration. Excessive dose can result in hypotention.

The starting dose is 10mg to 20mg three times a day. The usual effective dose range is 10-20mg three times daily. If higher dosages is necessary, the dose can be increased in stages up to maximum 60mg daily.

Hypertensive emergencies :

The recommended dose for the treatment of hypertensive emergencies is 20mg and if further reduction in blood pressure is required, then another 10mg may be given after a period of 30 minutes.

Lower dosage may be required in elderly patients as a result of reduced drug clearance.

For hypertension, the dose used should not exceed 60mg daily.

OVERDOSAGE, SYMPTOMS AND TREATMENT

No antidote is available. Gastric lavage is considered in the event that symptoms of hypotension, tachycardia or bradycardia, flushing, headaches, metabolic acidosis, hyperglyceamia, cardiogenic shock with pulmonary oedema, hypoxia and disturbances of consciousness to the point of coma. Medicinal charcoal may be used for irrigation of the small intestines. Plasmapheresis is preferred over dialysis as nifedipine is not dialyzable. The proceeding treatment is symptomatic and supportive. Fluid administration must be carried out with caution as this may cause volume overload.

PRESENTATION

Nudipin 10 is available in 10mg strength. Packed in a blister pack containing 10 uncoated tablets, 10 blisters in carton / 100 blisters in carton.

STORAGE CONDITION

Store below 30°C. Protect from light.

SHELF LIFE

Nudipin 10 must be used within 36 months from the date of manufacture.

Manufactured by :

SAI MIRRA INNOPHARM PVT. LTD.
288, 298 & 299, SIDCO Estate
Ambattur, Chennai 600098.
Tamil Nadu, India

Product Registration Holder :

MEDIDATA SDN. BHD.
36, Jalan PJS 8/6,
Sunway Mentari
46150 Petaling Jaya,
Selangor Darul Ehsan
Tel No : 03 5635 8780
Fax No : 03 5635 8528/ 5635 8548

Date of Revision:
October 2024

INNDP4

Sai Mirra innopharm

Brand Name: Nudipin	Client: Medidata SDN BHD, Malaysia	Date: 30-10-2024
Generic Name: Nifedipine 10mg	Spec: 60 GSM Maplitho	Item Code: INNDP4
Pack Insert Size: Open Size: 215 x 140mm After Folding Size: 110 x 70mm	Language: English	Software: .CDR X5
Colour: Black		Packing: 1000 Tablets
Remarks:		

Regulatory Department	Quality Assurance (QA)	Quality Control (QC)	Production