

SPMC NIMODIPINE TABLETS BP 30mg

PRESENTATION:

Nimodipine Tablets BP 30mg:

Packs of 30'S tablets bulk and 3X10'S tablets Blister Each tablets light Orang, circular, double convex tablets of 10.0 mm diameter with "SPC" or "SPMC" letters on one side and score mark on reverse. Each film-coated tablet contains 30 mg Nimodipine.

DRUG ACTION:

Nimodipine is a dihydropyridine calcium channel Blocker.

INDICATIONS AND DOSE:

Prevention of ischaemic neurological defects following Aneurysmal subarachnoid haemorrhage

Adult: 60 mg every 4 hours, to be started within 4 days of aneurysmal subarachnoid haemorrhage and Continued for 21 days

CAUTIONS:

Cerebral oedema. Hypotension. Severely raised intracranial pressure Careful monitoring of BP and pulse rate.

PREGNANCY:

Advises use only if potential Benefit outweighs risk.

BREAST FEEDING:

Advises avoid present in milk.

HEPATIC IMPAIRMENT:

Monitoring Elimination reduced in cirrhosis—monitor blood pressure.

RENAL IMPAIRMENT:

Monitoring with intravenous use Manufacturer advises monitor renal function closely in renal impairment.

DIRECTIONS FOR ADMINISTRATION:

Avoid concomitant administration of nimodipine infusion and tablets. with oral use for administration by mouth, tablets may be crushed or halved but are light sensitive—administer immediately.

CONTRAINDICATIONS:

Nimodipine must not be administered in case of hypersensitivity to the active substance. Nimodipine should not be administered to patients during or within one month of a myocardial infarction or an episode of unstable angina. The use of nimodipine in combination with rifampicin or the antiepileptic drugs, phenobarbital, phenytoin or carbamazepine is contraindicated as the efficacy of Nimodipine tablets could be significantly reduced when concomitantly administered.

SIDE-EFFECTS

<u>Uncommon</u> Thrombocytopenia. Vasodilation <u>Rare or very rare</u> Bradycardia. Ileus

IMPORTANT SAFETY INFORMATION SAFE PRACTICE:

Nimodipine has been confused with Amlodipine; care must be taken to ensure the correct drug is prescribed and dispensed.

DRUG INTERACTIONS:

Plasma concentration and efficacy may be significantly reduced when administered with strong CYP3A4 inducers (e.g. rifampicin, carbamazepine, phenobarbital, and phenytoin). May increase serum levels and toxicity of phenytoin. Increased plasma concentrations with cimetidine or sodium valproate. **Potentially Fatal:** Increased risk of significant hypotension with concomitant potent CYP3A4 inhibitors (e.g. clarithromycin, ritonavir, ketoconazole, nefazodone).

OVERDOSEGE:

Symptoms of intoxication

Symptoms of acute overdosage to be anticipated are marked lowering of the blood pressure, tachycardia, bradycardia and (after oral administration) gastrointestinal complaints and nausea.

Treatment of intoxication

In the event of acute overdosage, treatment with Nimotop must be discontinued immediately. Emergency measures should be governed by the symptoms. Gastric lavage with addition of charcoal should be considered as an emergency therapeutic measure. If there is a marked fall in blood pressure, dopamine or noradrenaline can be administered intravenously. As no specific antidote is known, subsequent treatment for other side effects should be aimed at the most prominent symptoms.

STORAGE:

Keep a cool & dry place. Store below 30°C in the original package in order to protect from moisture & Light. Keep all medicines away from children.

Manufactured by: State Pharmaceuticals Manufacturing Corporation No. 11, Sir John Kotalawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka.