

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

Rx

## Nimodipine Infusion BP

For IV Infusion use only.

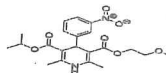
Composition:-

Each 50ml Contains:-		
Nimodipine	BP	10 mg
Water for Injection	IP	q.s

Description:-

Nimodipine infusion is a sterile solution of Nimodipine in Water for Injection for intravenous infusion administration.

Nimodipine infusion belongs to the class of pharmacological agents known as calcium channel blockers. Nimodipine is 2-methoxyethyl 1-methylethyl(4RS)-2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate. It has a molecular weight of 418.4 and a molecular formula of  $C_{21}H_{26}N_2O_6$ . And the structural formula is:



### PHARMACOLOGY

#### Pharmacokinetics

Nimodipine is rapidly absorbed from the gastrointestinal tract after oral doses but undergoes extensive first-pass metabolism in the liver. The oral bioavailability is reported to be about 13%. Nimodipine is more than 95% bound to plasma proteins. It crosses the blood-brain barrier, but concentrations in CSF are lower than those in plasma. Nimodipine is extensively metabolised in the liver. It is excreted in faeces via the bile, and in urine, almost entirely as metabolites. The terminal elimination half-life is reported to be about 9 hours but the initial decline in plasma concentration is much more rapid, equivalent to a half-life of 1 to 2 hours.

#### Dosage and Administration

Nimodipine is a dihydropyridine calcium-channel blocker that has the general properties of nifedipine, but acts particularly on cerebral blood vessels. It is used in cerebrovascular disorders (see below), particularly in the prevention and treatment of ischaemic neurological deficits after aneurysmal subarachnoid haemorrhage.

To reduce the incidence and severity of neurological deficit after aneurysmal haemorrhage nimodipine is given orally in a dose of 60 mg every 4 hours. Treatment should begin within 4 days of onset of haemorrhage and should continue for 21 days. In patients with hepatic impairment the dose may be reduced (see below) and blood pressure should be closely monitored. If cerebral ischaemia occurs or has already occurred, neurological deficit may be treated by intravenous infusion of nimodipine. It should be given via a bypass into a running intravenous infusion into a central vein. The initial dose should be nimodipine 1 mg/hour for 2 hours, increased (provided that no severe decrease in blood pressure occurs) to 2 mg/hour. The starting dose should be reduced to 500 micrograms/hour or even lower if necessary, in patients weighing less than 70 kg and in those with unstable blood pressure; a similar reduction in dosage has been suggested in hepatic impairment, and blood pressure should be closely monitored.

Treatment should be started as soon as possible and continued for at least 5 and no more than 14 days; if the patient has already received oral nimodipine, the total duration of nimodipine use should not exceed 21 days.

#### Administration in hepatic impairment

The clearance of nimodipine is reduced in patients with cirrhosis, and blood pressure should be closely monitored in such patients. US licensed product information recommends that the oral dose of nimodipine should be halved to 30 mg every 4 hours in patients with hepatic cirrhosis. Some manufacturers have also suggested a reduction in the initial intravenous dose to 500 micrograms or less per hour.

#### Cerebrovascular disorders

Nimodipine is used intravenously in the prevention and treatment of ischaemic neurological deficits caused by arterial vasospasm after aneurysmal subarachnoid haemorrhage, although the evidence for benefit after intravenous use is limited.

1 Nimodipine has also been used for traumatic subarachnoid haemorrhage.

2 but results have been mixed.3, 4 In addition to dilating cerebral blood vessels and improving cerebral blood flow, nimodipine may also prevent or reverse ischaemic damage to the brain by limiting transcellular calcium influx.

These effects have led to the investigation of nimodipine in other conditions associated with cerebral ischaemia. Studies 5, 6 of nimodipine given orally after ischaemic stroke have produced conflicting results. A meta-analysis7 of controlled studies suggested that nimodipine is beneficial if given within 12 hours of stroke onset but a further study8 failed to confirm these findings. In a controlled study 9 of 155 patients suffering a cardiac arrest, nimodipine was given by intravenous infusion for 24 hours. Nimodipine had no effect on overall survival; although it did improve survival of patients in whom advanced life support was delayed for more than 10 minutes after arrest. Nimodipine has also been tried in dementia. Two multicentre studies10 involving a total of 755 patients with dementia of vascular or degenerative origin given nimodipine for up to 6 months reported improvements in cognitive function and disability, and a systematic review11 concluded that nimodipine could be of some benefit in patients with various forms of dementia.

#### Warnings and Precautions

Caution should be exercised in patients with history of heart, liver or kidney disease, any allergy, recent head injury, who are taking other medications, elderly, children, during pregnancy and breastfeeding. It may cause dizziness, lightheadedness or drowsiness, do not drive a car or operate machinery while taking this medication.

Avoid alcohol consumption.

Monitor blood pressure regularly while taking this medication.

#### Side effects:-

**Central Nervous System:** Dizziness, lightheadedness, headache and depression.

**Heart:** Flushing, fast/slow heart rate, fainting and low blood pressure.

**Gastrointestinal:** Heartburn, stomach upset, constipation, nausea and vomiting.

**Allergic reactions:** Rash, difficulty in swallowing/breathing and swelling of the face/eyes, lips, tongue, arms or legs.

#### Children and adolescents

Do not give Nimodipine Infusion to children under the age of 18 as the safety and efficacy of Nimodipine Infusion have not been established.

#### Driving and using machines

Nimodipine Infusion may make you feel less alert, or dizzy. Do not drive or operate machinery if you are affected in this way. The amount of alcohol in the solution may also make you feel less alert.

If you continue your treatment with Nimodipine do not drive or operate machinery if you think you might be affected.

#### Overdose

If someone has overdosed and has serious symptoms such as passing out or trouble breathing call the Doctor as emergency. Or poison control centre.

#### Missed Dose

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

#### Precautions

Before taking nimodipine, tell your doctor or pharmacist if you are allergic to it; or to other dihydropyridine calcium channel blockers (such as amlodipine, felodipine); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially dizziness, or swelling of ankles/feet. Dizziness can increase the risk of falling.

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

This medication passes into breast milk. Consult your doctor before breast-feeding.

**Storage:** - Store in a dry place below 25°C. Protect from light, do not allow freezing.

**Improper Storage** may be deteriorate the product

Keep the medicine out of reach of children.

**Presentation:** - Each pack contain,

Each vial contains 10 mg/50 ml Solution for infusion

Mfg. in India by : Pace Biotech  
(An ISO 9001 : 2015, GMP & GLP Certified Co.)  
Surajpur, Poonia Sahib, Dist.- Sirmour (H.P.) - 173001