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What *Nimotop* is used for

Prevention and treatment of a decrease in brain, spinal cord, muscle or nerve function caused by blood loss associated with the narrowing of blood vessels in the brain following a stroke. *Nimotop* tablets are prescribed after *Nimotop* infusion solution is given to a patient.

How *Nimotop* works

Nimotop contains *nimodipine*, which belongs to a group of medicines called calcium channel blockers. *Nimotop* tablets are used to prevent changes in brain function after bleeding around the brain (subarachnoid haemorrhage).

Before you use *Nimotop*

- When you must not use it

Do not take *Nimotop* tablets:

- At the same time as you are getting *Nimotop* solution through a drip. The tablets have been prescribed as a convenient way to continue your treatment after the drip is stopped.
- If you are allergic to *nimodipine* or any of the ingredients in this product.
- If you are taking rifampicin (an antibiotic), phenobarbital, phenytoin or carbamazepine (three medicines most commonly used to treat epilepsy).

Tell your doctor and do not take *Nimotop* tablets if any of these apply to you.

Pregnancy

If you are pregnant or are planning a family, tell your doctor before taking *Nimotop*. Follow his/her instructions carefully.

Lactation

Do not breastfeed while taking *Nimotop* tablets.

- Before you start to use it

Inform your doctor:

- If you have had a heart attack within the last month.
- If you have generalized brain edema (elevated water content of the brain or increased brain pressure)
- If you have low blood pressure
- If you had a head injury, which caused bleeding around the brain (traumatic subarachnoid haemorrhage).
- If you suffer from angina (chest pain) and notice an increase in the frequency and severity of attacks.

- Taking other medicines

- You will not be given *Nimotop* tablets if you are receiving *Nimotop* Solution.
- Tell your doctor about any other medicines that you are taking, or took recently. This includes any products you bought without a prescription.
- Some medicines may affect the way *Nimotop* works. Tell your doctor if you are taking:
 - High blood pressure tablets such as diuretics, beta blockers, ACE inhibitors, other calcium channel blockers and alpha blockers.
 - An anti-ulcer medicine called cimetidine or an anti-epilepsy medicine called *sodium valproate*. These medicines may increase the effect of *Nimotop* tablets.
 - The anti-depressant medicine *fluoxetine* or *nefazodone*.
 - The anti-HIV medicine *zidovudine* (AZT).
 - The HIV protease inhibitor medicines such as, *ritonavir*.
 - Macrolide antibiotics such as erythromycin
 - Azole antifungals, such as ketoconazole.
 - The combination antibiotic quinupristin / dalfopristin.

How to use *Nimotop*

- How much to use

- Take the tablets as prescribed by your doctor.

- The usual dose is 2 tablets, every four hours, this gives a maximum daily dose of 12 tablets (360mg).
- Keep taking the tablets for as long as your doctor has told you to. Swallow the tablets with a little water. Do not take more than your doctor has prescribed.

- When to use it

The interval between doses must not be less than 4 hours. *Nimotop* can be taken before or after a meal.

- How long to use it

Continue taking *Nimotop* for as long as your doctor recommends.

- If you forget to use it

Take your normal dose immediately and carry on taking that day's tablets at 4-hour intervals. Do not take a double dose to make up for the missed tablets.

- If you use too much (overdose)

Get medical help immediately and, if possible, take your tablets with you. Taking too much *Nimotop* may cause low blood pressure (you may feel faint), heartbeats that are faster or slower than usual and feeling sick.

While you are using it

- Things you must do

Keep this leaflet. You may need to read it again. If you have more questions, ask your doctor or pharmacist. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Nimotop*.

- Things you must not do

- Do not drink grapefruit juice or eat grapefruit while taking *Nimotop* tablets.
- Do not start taking *Nimotop* tablets within 4 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Grapefruit juice is known to increase the blood levels of the active

ingredient, *nimodipine*. This effect can last for at least four days.

- Do not give *Nimotop* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Your doctor will take special care:

- If you have liver disease. You will probably need to have your blood pressure measured regularly.

Driving and using machines

Nimotop tablets may make you feel dizzy. Do not drive or operate machinery if you are affected in this way.

Side effects

Like all medicines, *Nimotop* can have side effects although not everybody gets them.

Potentially serious side effects

If you experience:

- allergic reaction
- low blood pressure (may cause dizziness)
- slow heartbeat

Contact your doctor immediately as these side effects can sometimes be serious.

Less serious side effects

In addition to the serious side effects listed above, these are the other less serious side effects of *Nimotop* tablets:

Uncommon side effects

(These may affect less than 1 in 100 people)

- rash
- headache
- fast heartbeat
- flushing, sweating, feeling of warmth
- feeling sick (nausea)

Rare side effects

(These may affect less than 1 in 1,000 people)

- constipation (lack of bowel movement)
- slight rise in liver enzymes (this will show up in blood tests)

If you get side effects

Tell your doctor if any side effect gets severe, or if you get any effects not listed in this leaflet. He or she may cut down or stop your treatment.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of *Nimotop*

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not use the tablet after the expiry date which is marked on both the outer carton and on each blister strip of tablets.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Film-coated tablet. Yellow, round biconvex tablets with “SK” marked on one side and the Bayer cross marked on the other side.

- Ingredients

- Active ingredient
Nimodipine 30mg

- Inactive ingredients
Microcrystalline cellulose, hypromellose, macrogol 4000, maize starch, povidone, crospovidone, magnesium stearate and the colourings titanium dioxide (E171) and iron oxide yellow (E172).

- MAL number(s):

MAL19940001A

Manufacturer

Bayer Pharma AG, 51368 Leverkusen, Germany

Product Registration Holder

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