

Package leaflet: Information for the user

Nimotop[®] 30 mg Tablets

Nimodipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nimotop tablets are and what they are used for
2. What you need to know before you take Nimotop tablets
3. How to take Nimotop tablets
4. Possible side effects
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1 What Nimotop tablets are and what they are used for

Nimotop tablets contains nimodipine, which belongs to a group of medicines called *calcium antagonists*.

Nimotop tablets are used to prevent changes in brain function after bleeding around the brain (*subarachnoid haemorrhage*).

2 What you need to know before you take Nimotop tablets

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 have had a heart attack** within the last month.
 - **If you suffer from angina** and notice an increase in the frequency and severity of attacks.
 - **If you are allergic to nimodipine** or any of the ingredients of this medicine (listed in section 6).
 - **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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nimotop tablets

- **If you had a head injury**, which caused bleeding around the brain (*traumatic subarachnoid haemorrhage*).
- **If you have fluid in the brain or severely raised pressure in your skull.** Your doctor will be able to advise you about this.
- **If you have low blood pressure.**
- **If you have liver disease.** You will probably need to have your blood pressure measured regularly.

➔ **Tell your doctor before you take Nimotop tablets**, if any of these apply to you.

Children and adolescents

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

Other medicines and Nimotop tablets

You will not be given Nimotop tablets if you are receiving **Nimotop Solution**.

You are not to be given rifampicin (an antibiotic), **phenobarbital**, **phenytoin**, or **carbamazepine** (anti-epileptic drugs) if you are taking Nimotop tablets.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way Nimotop tablets works. **Tell your doctor** if you are taking:

- **High blood pressure tablets** (including nifedipine, diltiazem, verapamil, alpha-methyl dopa, alpha-blockers or **beta-blockers**). Nimotop tablets may increase the effect of these medicines.
- An **anti-ulcer** drug called **cimetidine** or an **anti-epilepsy** drug called **sodium valproate**. These medicines may increase the effect of Nimotop tablets.
- The anti-depressant drugs fluoxetine or nefazodone.
- The **anti-HIV** drug **zidovudine** (AZT).
- The **HIV protease inhibitor drugs** indinavir, ritonavir, nelfinavir or saquinavir.
- The antibiotic erythromycin or the anti-fungal drugs ketoconazole, itraconazole or fluconazole.
- The antibiotic drug combination quinupristin / dalfopristin.

Nimotop tablets with food and drink

You can take Nimotop tablets with or without food.

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. Also, do not drink grapefruit juice or eat grapefruit whilst taking Nimotop tablets. Grapefruit juice is known to increase the blood levels of the active ingredient, nimodipine. This effect can last for at least four days.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Follow his/her instructions carefully.

Do not breast-feed while taking Nimotop tablets.

If you are trying to father a child, talk to your doctor. Medicines like Nimotop tablets can sometimes affect male fertility.

Driving and using machines

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

3 How to take Nimotop tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- **The recommended dose** is 2 tablets, every four hours, this gives a maximum daily dose of 12 tablets (360 mg).
- **Keep taking the tablets for as long as your doctor has told you to.** This may be for up to 21 days.

Swallow the tablets with a little water.

Do not take more than your doctor has prescribed.

If you take more Nimotop tablets than you should

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

If you forget to take the tablets

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 forgotten tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Potentially serious side effects

If you experience:

- Signs of allergic reaction such as swelling of the face, lips, tongue or throat, difficulty breathing, rash, itching, nausea or vomiting
- low blood pressure (may cause dizziness)
- slow heartbeat
- easier bruising and bleeding caused by a reduced number of blood platelets

→ **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)

Not known: frequency cannot be estimated from the available data

- low level of oxygen in body tissues

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nimotop tablets

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on both the outer carton and on each blister strip of tablets after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Nimotop tablets contain

The active substance is nimodipine. Each film-coated tablet contains 30 mg of nimodipine. The other ingredients are microcrystalline cellulose, hypromellose, macrogol, maize starch, povidone, crospovidone, magnesium stearate and the colourings titanium dioxide (E171) and iron oxide yellow (E172).

What Nimotop tablets looks like and contents of the pack

- Nimotop tablets are film-coated tablets. The tablets are yellow, round biconvex tablets with “SK” marked on one side.
- Nimotop is available in a pack of 100 tablets.

The tablets come in boxes of 100, but your doctor will prescribe as many as you need.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Laboratoire X.O, 170 Bureaux de la Colline, 92213 Saint-Cloud Cedex, France

Manufacturers:

Bayer AG, Leverkusen, Germany

Or

Haupt Pharma Münster, Münster, Germany

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