Package leaflet: Information for the user

Nimotop 0.02% w/v Concentrate for Solution for Infusion
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, pharmacist or nurse.

-If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nimotop is and what it is used for

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

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

2. What you need to know before you are given Nimotop

Do not take Nimotop
You will not be given Nimotop:

- **If you are allergic to** nimodipine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Nimotop

Your doctor will take special care:

- **While you are having a heart attack.**
- **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 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.
- **If you have kidney problems** and/or you have been given drugs which may alter kidney function (e.g. aminoglycosides, cephalosporins, furosemide). Your doctor may need to monitor your kidney function during treatment.
- I**f you are susceptible to alcohol** (see section 2 Nimotop contains alcohol (ethanol)')

Tell your doctor before you take Nimotop if any of these apply to you.

Children and adolescents
Nimotop is not recommended for use in children and adolescents under 18 years of age.

Other medicines and Nimotop Concentrate for Solution for Infusion
You will not be given Nimotop Concentrate for Solution for Infusion if you are taking **Nimotop tablets.**

You are not to be given injectable beta-blockers if you are given Nimotop.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes any products you bought without a prescription. It's especially important to tell your doctor about these medicines:

- **High blood pressure tablets** (including alpha-methyl dopa, ACE-inhibitors such as lisinopril or perindopril) or **beta-blockers** such as atenolol or propranolol. Nimotop may increase the effect of these medicines.
- **Other calcium antagonists for high blood pressure or chest pain** (including nifedipine, diltiazem, verapamil).
- **Diuretics for high blood pressure or water retention** such as furosemide or spironolactone.
- **Other drugs for high blood pressure known as PDE5 inhibitors** including enoximone.
- **Drugs for the treatment of erectile dysfunction** including sildenafil, tadalafil, vardenafil.
- **Other drugs for high blood pressure or enlargement of the prostate** including doxazosin and tamsulosin.
- An **anti-ulcer** drug called **cimetidine** or an **anti-epilepsy** drug called **sodium valproate.** These medicines may increase the effect of Nimotop.
- **Other medicines most commonly used to treat epilepsy (phenobarbital, phenytoin, carbamazepine)** as the effect of Nimotop could be reduced.
- The antidepressant drugs fluoxetine, nortriptyline 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.
- Any other medicines you are on **whose effects may be changed by the amount of alcohol in Nimotop .** Your doctor should know which these are (for example, metronidazole or tinidazole). Talk to your doctor, pharmacist or nurse if you are taking other medicines.

Nimotop with food and drink
Do not drink grapefruit juice or eat grapefruit while taking Nimotop .

Do not start treatment with Nimotop 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 whist being treated with Nimotop. 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 using this medicine. Follow his/her instructions carefully. **Do not breastfeed** while you are being treated with this medicine.

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

Driving and using machines

Nimotop 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 this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react.
If you continue your treatment with Nimotop (for example if your doctor prescribes tablets) do not drive or operate machinery if you think you might be affected.

Nimotop contains sodium
This medicine contains 23 mg sodium (main component of cooking/table salt) per 50 ml bottle. This is equivalent to 1.15 % of the recommended maximum daily dietary intake of sodium for an adult.

Nimotop contains alcohol (ethanol)
This medicine contains 2 g of alcohol (ethanol) in each hourly dose of 10 ml (23.7 vol%). The amount in 10 ml of this medicine is equivalent to 50 ml beer or 20 ml wine.
The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.
The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.
Because this medicine is given slowly by continuous infusion, the effects of alcohol may be reduced.
If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.
If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

3. How you are given Nimotop

Nimotop Concentrate for Solution for Infusion is given by a doctor or nurse, as a slow injection through a vein into the bloodstream.

The recommended dose in adults is 5 ml per hour in the first two hours of treatment. This will be increased to 10 ml per hour, if there is no sign of a drop in blood pressure.

Treatment will last for at least 5 days, up to a maximum of 14 days. After the intravenous therapy, you may be given Nimotop tablets for a further period of time, but the total length of treatment with nimodipine (Nimotop Concentrate for Solution for Infusion followed by Nimotop tablets) will not exceed 21 days.

If you weigh less than 70 kg or have **unstable blood pressure**, your doctor will calculate the dose of Nimotop required.

If you are given more Nimotop than you should

The amount of Nimotop you receive is carefully controlled by your doctor. It is highly unlikely that you will be given too much medicine.

- **Tell your doctor if you feel faint or if your heartbeats are slower or faster than normal or if you feel sick**.

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

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:
· allergic reaction (signs include rash - skin hypersensitivity, swallowing or breathing problems, swelling of your lips, face, throat or tongue)
· 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:

Uncommon side effects
(*may affect up to 1 in 100 people*)
- rash
- headache
- fast heartbeat
- flushing, sweating, feeling of warmth
- feeling sick (*nausea*).

Rare side effects
(*may affect up to 1 in 1,000 people*)
- constipation (lack of bowel movement)
- a slight rise in liver enzymes (this will show up in blood tests)
- pain and or swelling in a vein (possibly caused by a blood clot) where the needle was inserted.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website:
www.medicinesauthority.gov.mt/adrportal

5. How to store Nimotop

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

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

Do not store above 25°C.

Store in the outer carton until just before use to protect from light. Your doctor or hospital pharmacist will store Nimotop appropriately before it is used.

For single use only. 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 contains
-The active substance is nimodipine.

- The other ingredients are ethanol (see section 2 “Nimotop contains alcohol (ethanol)”), macrogol, sodium citrate (see section 2 “Nimotop contains sodium”), citric acid and water for injection.

What Nimotop looks like and contents of the pack
Nimotop Concentrate for Solution for Infusion is a clear, yellow solution.

Each glass vial contains 10mg of nimodipine in 50ml of solution, 0.2 mg/ml (0.02% solution).

Each carton contains
1 x 50ml vial concentrate for solution for infusion (sterile concentrate) with 1 polyethylene infusion line.

Nimotop is available in packs containing 1 bottle and in multi-packs comprising 5 cartons, each containing 1 bottle. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Bayer Limited, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland
Manufacturer:
Bayer AG
Kaiser-Wilhelm-Allee
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