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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

Package leaflet: Information for the user

Nimotop® 0.02% 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 or pharmacist.
- This medicine has been prescribed for you only.
- 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 solution is and what it is used for

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

Nimotop solution 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 solution

Do not take Nimotop solution

You should not be given Nimotop solution:

- **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).

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

Warnings and precautions

Talk to your doctor or pharmacist before receiving Nimotop solution

- **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.
- **If you have kidney problems.** Your doctor may want to monitor your kidney function during treatment.
- **If you are susceptible to alcohol.**
- **If you are on a controlled salt (sodium) diet.**

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

Children and adolescents

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

Other medicines and Nimotop solution

You will not be given Nimotop solution if you are taking **Nimotop tablets**.
You are not to be given injectable beta-blockers if you are given Nimotop solution.

Tell your doctor if you are taking, have recently taken or might take any other medicines. It's especially important to tell your doctor about these medicines:

- **high blood pressure tablets** (including nifedipine, diltiazem, verapamil, methyldopa, alpha-blockers or **beta-blockers**, such as atenolol, propanolol). Nimotop solution 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 solution.
- the antidepressant drugs fluoxetine or nefazodone.
- medicines causing harm to the kidney **(nephrotoxic medicines)** such as aminoglycosides, cephalosporins, furosemide. Your doctor will monitor your kidney function during treatment.
- the **anti-HIV** drug **zidovudine** (AZT).
- the **HIV protease inhibitor drugs** indinavir, ritonavir, nelfinavir or saquinavir.
- the antibiotic erythromycin or the anti-fungal drug ketoconazole.

- the antibiotic drug combination quinupristin / dalfopristin.
- any other medicines you are on **whose effects may be changed by the amount of alcohol in Nimotop solution**. Your doctor should know which these are (for example, metronidazole or tinidazole).

Nimotop solution with food and drink

Do not drink grapefruit juice or eat grapefruit while taking Nimotop solution.

Do not start treatment with Nimotop solution 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 being treated with Nimotop solution. 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 or breast-feeding, 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 you are being treated with Nimotop solution.

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

Driving and using machines

Nimotop solution 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 Nimotop (for example if your doctor prescribes tablets), do not drive or operate machinery if you think you might be affected.

Nimotop Solution contains 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.

Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines.

The amount of alcohol in this medicinal product may impair your ability to drive or use machines.

Nimotop Solution contains sodium citrate
This medicine contains 23 mg sodium (main component of cooking/table salt) per 50ml bottle or 115 mg sodium per 250 ml bottle. This is equivalent to 1.15 % or 5.75 %, respectively, of the recommended maximum daily dietary intake of sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

3. How you are given Nimotop solution

Nimotop solution is given by a doctor or nurse, as a slow injection through a vein into the bloodstream.

The recommended dose is 5 ml per hour in the first two hours of treatment. This will be increased to 10ml 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 solution 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 solution required.

If you are given more Nimotop solution than you should

The amount of Nimotop solution 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.**

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 heart beat
- 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 solution:

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

Rare side effects
(These 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. 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.
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Nimotop solution

Keep this medicine out of the sight and reach of children.
Store below 25°C and protect from light.
Store in the outer carton until just before use. Your doctor or hospital pharmacist will store Nimotop solution appropriately before it is used.

This medicine should not be used after the expiry date which is stated on both the outer carton and on each vial 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 solution contains

The active substance is nimodipine.
The other ingredients are ethanol, macrogol, sodium citrate, citric acid and water for injection.

What Nimotop solution looks like and contents of the pack

Each glass vial contains 10mg of nimodipine in 50ml of solution (0.02% solution).
Each pack contains
1 x 50ml vial with 1 polyethylene infusion line *or*
5 x 50ml vials with 5 polyethylene infusion lines.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Bayer plc, 400 South Oak Way, Reading, RG2 6AD

Manufacturer: Bayer AG, Leverkusen, Germany

This leaflet was last revised in June 2020.

Marketing authorisation number: PL 00010/0138