Package leaflet: information for the patient
Nimotop®, 30 mg, film-coated 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 IS AND WHAT IT IS USED FOR
Nimotop contains the active substance nimodipine. Nimotop is a medicine that counteracts the effects of vascular spasms after brain haemorrhages (cerebral agent; calcium channel blocker).
Nimotop is used for prevention and treatment of ischaemic neurological deficits due to cerebral vasospasms following aneurysmal subarachnoid haemorrhage; the film-coated tablets are taken after prior administration of Nimotop, solution for infusion.
Explanation: Brain haemorrhages can cause spasms in the blood vessels. This can lead to poor blood circulation through the affected areas of the brain and thus damage the nervous system. Nimotop is used to prevent such damage or treat it.

2 - WHAT YOU NEED TO KNOW BEFORE YOU TAKE NIMOTOP
Do not take Nimotop
- if you are allergic to nimodipine or any of the other ingredients of this medicine (listed in section 6).
- if you are also using rifampicin (an antibiotic / medicine for tuberculosis) or phenobarbital, phenytoin or carbamazepine (medicines for epilepsy), as the effectiveness of Nimotop, film-coated tablets can be significantly reduced by these medicines (see section 2, “Other medicines and Nimotop”).

Warnings and precautions
Talk to your doctor or pharmacist before taking Nimotop.
Take special care with Nimotop:
- if tissue fluid levels in your brain are high (generalised cerebral oedema)
- if your brain pressure is relatively high
- if you have low blood pressure (systolic blood pressure below 100 mm Hg)

In patients with unstable angina pectoris or within the first four weeks after an acute heart attack, the treating doctor should weigh up the potential risk (e.g. reduced blood flow through the coronary arteries and myocardial ischaemia) against the benefit (e.g. improvement in blood flow through the brain).

The active substance in Nimotop, nimodipine, is broken down with the help of a certain enzyme system (cytochrome P450 3A4). This enzyme system can be inhibited or enhanced by other medicines. As a result, the effects and side effects of Nimotop can be changed (see section 2, "Other medicines and Nimotop").
If you are taking Nimotop, film-coated tablets at the same time as other medicines that inhibit this enzyme system, this can enhance the effects of Nimotop as well as increase its side effects. For example, this includes the following medicines:

- certain antibiotics (macrolide antibiotics, e.g. erythromycin)
- certain HIV medicines (e.g. ritonavir)
- certain antifungal medicines (e.g. ketoconazole)
- nefazodone and fluoxetine (antidepressants)
- quinupristin/dalfopristin (antibiotics)
- cimetidine (medicine for gastrointestinal ulcers)
- valproic acid (medicine for epilepsy)

If Nimotop, film-coated tablets are used at the same time as any of these medicines, your blood pressure should be monitored and, if necessary, a reduction in the Nimotop dose should be considered.

Children and adolescents
The safety and efficacy of Nimotop have not been established in children and adolescents under 18 years of age. As there is insufficient experience to date concerning use in children and adolescents, nimodipine is not yet intended for treatment of this age group.

Other medicines and Nimotop
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.
The active substance in Nimotop, nimodipine, is broken down with the help of a certain enzyme system (cytochrome P450 3A4). In principle, combined use of medicines that affect this system can therefore lead to interactions between these medicines and nimodipine.

<u>Reduced Nimotop effects due to other medicines:</u>
Do not use Nimotop at the same time as rifampicin (an antibiotic/medicine for tuberculosis) or phenobarbital, phenytoin or carbamazepine (medicines for epilepsy) (see section 2, "Do not take Nimotop").

<u>Enhanced Nimotop effects and side effects due to other medicines:</u>
If you are using Nimotop at the same time as the following other medicines, your blood pressure should be monitored and, if necessary, a reduction in the Nimotop dose should be considered (see also section 2, "Warnings and precautions"):

- certain antibiotics (macrolide antibiotics, e.g. erythromycin)
- certain HIV medicines (e.g. ritonavir)
- certain antifungal medicines (e.g. ketoconazole)
- fluoxetine and nefazodone (antidepressants). The effect and side effects of fluoxetine may also be altered.
- quinupristin/dalfopristin (antibiotics)
- cimetidine (medicine for gastrointestinal ulcers)
- valproic acid (medicine for epilepsy)

Further interactions with other medicinal products:

<u>Weakened Nimotop effect due to other medicines:</u>

- Nortriptyline (antidepressant)

<u>Change in the effects and side effects of other medicines due to Nimotop:</u>

- Zidovudine (anti-HIV medicine): The side effects of zidovudine may be increased.

- Medicines used to lower blood pressure: Nimotop can enhance the blood pressure-lowering effect of these medicines when used at the same time. However, if combination with any of these medicines should prove unavoidable, particularly careful patient monitoring is required.

Nimotop with food and drink
The effects and side effects of Nimotop can be increased by grapefruit juice. This effect lasts for at least 4 days after the last drink of grapefruit juice. Consumption of grapefruit or grapefruit juice close in time to Nimotop treatment should therefore be avoided.

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 or pharmacist for advice before taking this medicine.

Pregnancy
No studies have been carried out into the harmful effects of Nimotop on pregnancy. If Nimotop is to be used during pregnancy, the benefit and possible risks must therefore be carefully weighed up according to the severity of the clinical picture.

Breast-feeding
As nimodipine (the active substance in Nimotop) passes into breast milk, you should stop breast-feeding whilst using this medicine.

Fertility
During *in vitro* fertilisation, calcium antagonists have been associated in individual cases with reversible biochemical changes in the sperm head, which might lead to impaired sperm function. It is not known to what extent this finding is significant in short-term treatment.

Driving and using machines
In principle, Nimotop may impair the ability to drive and use machines in association with the possible onset of dizziness.

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

Dosage
Unless otherwise prescribed by the doctor, a daily dose of 6x 60 milligrams nimodipine - equivalent to 2 Nimotop film-coated tablets 6 times daily at four-hourly intervals - is recommended, after previous 5- to 14-day administration of Nimotop, solution for infusion.
If you experience side effects, your doctor will reduce the dose as necessary.
If you are also using other medicines that inhibit or enhance a certain enzyme system (cytochrome P450 3A4), an adjustment of the Nimotop dose may be required (see also section 2 “Other medicines and Nimotop”).
In cases of severe liver dysfunction, especially in cirrhosis of the liver, the effects and side effects, e.g. a decrease in blood pressure, may be more marked; in such cases, the dose may have to be reduced by the treating doctor and, if necessary, discontinuation of treatment should be considered.

Method of administration
Oral use.

How and when should you take Nimotop?
Take the film-coated tablets independently of meals with sufficient liquid (preferably 1 glass of water). Do not chew. Make sure there is a time interval of at least 4 hours between each dose. It is recommended that you do

not take the film-coated tablets lying down. Grapefruit juice should be avoided (see section 2 “Nimotop with food and drink”).

How long should you take Nimotop?
After finishing the 5- to 14-day infusion treatment with Nimotop, solution for infusion, you should take Nimotop, film-coated tablets for a period of about 7 days, according to general recommendations.
The treating doctor will decide on the duration of treatment in each individual case. This will depend on the severity and progression of your condition.

If you take more Nimotop than you should
Side effects may be increased as a result of an overdose, such as a relatively sharp drop in blood pressure, increased or decreased heart rate, as well as gastrointestinal complaints and nausea.
If you suspect an overdose, tell a doctor immediately, so that he/she can decide what to do next.
In the event of acute overdose, treatment with Nimotop must be stopped immediately.

Medical procedures in case of overdose
There is no known specific antidote to date; corrective action should be guided by the clinical symptoms. In the event of acute overdose, treatment with Nimotop should be stopped immediately. As an immediate therapeutic measure, gastric lavage (stomach pumping) with the addition of charcoal should be considered. If there is a sharp decrease in blood pressure, dopamine or noradrenaline should be intravenously administered.

If you forget to take Nimotop
Do not take a double dose next time to make up for a forgotten dose. Continue treatment at the prescribed dose.

If you stop taking Nimotop
Always talk to your doctor before you wish to suspend treatment with Nimotop, film-coated tablets, e.g. due to the onset of side effects, or end it before you should.
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.
In clinical studies, the following side effects were observed:

Uncommon (may affect up to 1 in 100 people):
Reduction in the blood platelet count, allergic reaction, skin rash, headache, faster heart rate, decrease in blood pressure, dilation of the blood vessels, nausea.

Rare (may affect up to 1 in 1,000 people):
Decrease in heart rate, bowel obstruction, temporary rise in liver enzyme values.

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

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 the blister and carton after “EXP”. The expiry date refers to the last day of that month
Storage conditions:
Not to be stored above 30°C

6. FURTHER INFORMATION

What Nimotop contains

- The active substance is nimodipine. One Nimotop film-coated tablet contains 30 milligrams of nimodipine.
- The other ingredients are: microcrystalline cellulose, maize starch, povidone K25, crospovidone, magnesium stearate, hypromellose, macrogol 4000, titanium dioxide (E171), iron (III) oxide-hydroxide (yellow, E172).

What Nimotop looks like and contents of the pack

Round, yellow, biconvex film-coated tablets, marked with the "Bayer cross" on one side and with "SK" on the other side.
Nimotop is available in original packs of 30, 50 and 100 film-coated tablets.
Not all packs may be marketed

Manufacturer and Marketing
Authorisation Holder:
Bayer AG
Kaiser-Wilhelm-Allee 1
51368 Leverkusen, Germany.

This leaflet was last revised in February 2017.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacist