PACKAGE LEAFLET
INFORMATION FOR THE USER

Nimotop®

Active ingredient: Nimodipine

Nimotop®, film-coated tablets
30 mg film-coated tablets
Active substance:
nimodipine

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. WHAT NIMOTOP IS AND WHAT IT IS USED FOR

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 - BEFORE YOU TAKE NIMOTOP

Do not take Nimotop
- if you are allergic (hypersensitive) to the active substance nimodipine or any of the other ingredients of Nimotop.
- 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 “Taking other medicines”).

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 “Taking other medicines”).
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
As there is insufficient experience to date concerning use in children and adolescents, nimodipine is not yet intended for treatment of this age group.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
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.
Reduced Nimotop effects due to other medicines:
Do not use Nimotop at the same time as rifampicin (an antibiotic / medicine for tuberculosis) or phenobarbital, phenytoin or carbamazepine (medicines for epilepsy) (see “Do not take Nimotop”).
Enhanced Nimotop effects and side effects due to other medicines:
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 “Take special care with Nimotop”):
- certain antibiotics (macrolide antibiotics, e.g. erythromycin)
- ritonavir (anti-HIV medicine)
- 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)

Weakened Nimotop effect due to other medicines:
- Nortriptyline (antidepressant)

Change in the effects and side effects of other medicines due to Nimotop:
- 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.

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

In-vitro fertilisation
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 Nimotop exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.

Dosage
Unless otherwise prescribed by the doctor, a daily dose of 6x 60 mg 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 No. 2, section “Taking other medicines”).
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 No. 2, section “Taking 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 have the impression that the effect of Nimotop is too strong or too weak, talk to your doctor or pharmacist.

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.

Effects 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nimotop can cause side effects, although not everybody gets them.
The following categories are used for expressing the frequency of side effects:
Very common: more than 1 in 10 patients treated
Common: 1 to 10 out of 100 patients treated
Uncommon: 1 to 10 out of 1,000 patients treated
Rare: 1 to 10 out of 10,000 patients treated
Very rare: less than 1 in 10,000 patients treated
Not known: cannot be estimated from the available data

Possible side effects
In clinical studies, the following side effects were observed:
Uncommon:
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:
Decrease in heart rate, bowel obstruction, temporary rise in liver enzyme values.
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.

5. HOW TO STORE NIMOTOP

Keep out of the reach and sight of children.
Do not use Nimotop after the expiry date which is stated on the blister and folding box 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, film-coated tablets contain
The active substance is nimodipine.
1 Nimotop film-coated tablet contains 30 mg nimodipine.
The other ingredients are:
microcrystalline cellulose,
maize starch,
povidone 25,
crospovidone,
magnesium stearate,
hypromellose,
macrogol 4000,
titanium dioxide (E171),
iron oxide hydrate (yellow iron oxide, E172).

What Nimotop, film-coated tablets look 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, film-coated tablets are available in original packs of 30, 50 and 100 film-coated tablets.

Manufacturer
Bayer Pharma AG
Site:
D-51368 Leverkusen, Germany.
This leaflet was last revised in
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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
Bayer Pharma AG , Germany
Bayer