



## Package Leaflet – information for the user

### Nimotop 30 mg Film-coated Tablets 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 more 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 effect not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What Nimotop tablets are
2. Before you take Nimotop tablets
3. How you take Nimotop tablets
4. Possible side effects
5. How to store Nimotop tablets
6. Further information

#### 1. What Nimotop tablets are

Nimotop 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. Before you take Nimotop tablets

##### Do not take Nimotop tablets:

- **At the same time as you are getting Nimotop sterile concentrate through a drip.** The tablets have been prescribed as a convenient way to continue your treatment after the drip is stopped.
- **If you are allergic to nimodipine** or any of the ingredients in this product. The ingredients are 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.

#### 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.

→ **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

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

**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 about any other medicines** that you are taking, or took recently. This includes any products you bought without a prescription.

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

- **High blood pressure tablets** (including alpha-methyl dopa, ACE-inhibitors such as lisinopril or perindopril) or **beta-blockers** such as atenolol or propranolol. Nimodipine tablets may increase the effect of these medicines. You are not to be given injectable beta-blockers if you are taking Nimotop tablets.
- **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 tablets.
- The anti-depressant 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.
- The antibiotic drug combination quinupristin / dalfopristin.

#### Food and drink with Nimotop tablets

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.

#### Fertility, pregnancy and breastfeeding

**If you are pregnant** or are planning a family, tell your doctor before taking Nimotop. Follow his/her instructions carefully.

**Do not breastfeed** while taking Nimotop tablets.

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

#### 3. How you take Nimotop tablets

Take the tablets as prescribed by your doctor.



- **The usual dose in adults** is 2 tablets, every four hours i.e. 6 times a day. This gives a maximum daily dose of 12 tablets (360 mg).
- In severe cases of impaired liver function your doctor may decide to reduce the dose or discontinue treatment.
- **Keep taking the tablets for as long as your doctor has told you to.** Nimotop tablets are generally recommended to be taken for about 7 days.

Swallow the tablets with a little water.

**Do not take more than your doctor has prescribed.**

**If you take too many tablets**

→ **Get medical help immediately** and, if possible, take your tablets with you. Taking too much Nimotop 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 missed tablets.

#### 4. Possible side effects

Like all medicines, Nimotop can have side effects – but 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 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 1000 people)*

- constipation (lack of bowel movement)
- slight rise in liver enzymes (this will show up in blood tests)

#### 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 via HPRC Pharmacovigilance, Earsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Nimotop tablets

##### Keep out of the reach and sight of children

Do not store above 30°C.

Do not use the tablets after the expiry date which is marked on both the outer carton and on each blister strip of tablets.

Don't dispose of medicines in waste water or household rubbish. If you find that you have tablets after their expiry date, return them to your local pharmacist (chemist) who will dispose of them properly. This helps the environment.

#### 6. Further information

##### What Nimotop tablets contain

Each Nimotop film-coated tablet contains 30 mg of the active ingredient nimodopine.

Nimotop tablets also contain:

##### Tablet core

Povidone,  
microcrystalline cellulose,  
maize starch,  
crospovidone,  
magnesium stearate.

##### Tablet coating

hypromellose,  
macrogol,  
titanium dioxide (E171),  
iron oxide yellow (E172).

#### What's in the pack

Each tablet is yellow and marked with the Bayer cross on one side and "SK" on the reverse

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

#### Marketing Authorisation holder:

Bayer Limited, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland

#### Manufacturer:

Bayer AG  
D51368 Leverkusen  
Germany

#### This leaflet was last revised:

September 2022

#### Product Authorisation Number:

PA1410/030/001  
AA639/02402