

NIMOTOP®

(NEE·moe·top)

nimodipine

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Nimotop. This leaflet does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nimotop against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again

WHAT NIMOTOP IS USED FOR

Nimotop tablets and infusion solution are used to prevent or to treat a lack of blood supply in the brain caused by narrowing of the blood vessels after a haemorrhage (burst blood vessel in the brain).

This medicine belongs to a group of drugs called calcium channel blockers. Nimotop works by relaxing the smooth muscle of the small blood vessels in the brain.

This allows narrowed vessels to open up, thereby increasing blood flow, reducing blood pressure, and improving circulation.

Your doctor may prescribe this medicine for another use. If you

want more information, ask your doctor.

If you have any further questions on your Nimotop treatment, or are unsure of the information, please see your doctor, nurse or dispensing pharmacist, who will be able to assist you.

BEFORE YOU TAKE NIMOTOP

When you must not take it

Do not take Nimotop tablets or infusion solution if you have an allergy to:

- nimodipine, the active ingredient in Nimotop
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take broken or discoloured tablets, or cloudy or discoloured infusion solutions.

Do not take Nimotop tablets if you are taking another medicine containing:

- phenobarbitone, phenytoin, carbamazepine or other anticonvulsants; medicines used to treat epilepsy or seizures.

- rifampicin, an antibiotic used to treat tuberculosis and other serious infections.

Do not take this medicine after the expiry date printed on the pack, blister or bottle.

The expiry date is printed on the carton, each blister and bottle after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- low blood pressure
- heart conditions
- fluid retention in the brain
- kidney or liver disease
- bowel obstruction

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

It is not recommended to give this medicine to a child under the age of 18 years.

Safety and effectiveness in children have not been established.

Nimotop infusion solution contains alcohol.

Tell your doctor if you suffer from alcoholism or impaired alcohol metabolism. Patients with liver disease, epilepsy, pregnant or breastfeeding should take into account that Nimotop infusion solution contains alcohol.

If you have not told your doctor, nurse or pharmacist about any of the above, tell them before you start taking Nimotop.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Nimotop may interfere with each other. These include:

- medicines used to lower your blood pressure and/or reduce water retention, such as frusemide
- medicines used to treat tuberculosis, such as rifampicin
- medicines used to treat epilepsy or seizures, such as carbamazepine, phenobarbitone, phenytoin, sodium valproate
- certain antibiotics, such as erythromycin, quinupristin/dalfopristin, aminoglycosides, cephalosporins
- medicines used to treat HIV infection and AIDS, such as ritonavir, zidovudine
- antifungals, such as ketoconazole
- medicines used to treat depression, such as nefazodone, fluoxetine, nortriptyline
- medicines used to treat heartburn, such as cimetidine
- medicines used to treat cancer, such as doxorubicin, vincristine

These medicines may be affected by Nimotop or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Your doctor, nurse or pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

You should not eat grapefruit or drink grapefruit juice while you are on Nimotop because this can increase the effects of it.

HOW TO TAKE NIMOTOP

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacist label, ask your doctor, nurse or pharmacist for help.

How much to take

Nimotop tablets:

The usual adult dose is 60 mg (2x30 mg) six times a day, every 4 hours for 7 days following Nimotop infusion treatment, OR 10-14 days when only tablets are used.

Remember: It is important to take your medicine as directed by your doctor. If you are unsure how to take your medicine ask your doctor.

Nimotop infusion solution:

The starting dose of Nimotop is 5 mL per hour for the first 2 hours and must be given with co-infusion solution. Then, if you have had no dramatic drop in blood pressure, your doctor may increase the dose to 10 mL per hour.

You should be given this treatment for 7-14 days only.

The dosage recommendations and duration of treatment is dependent upon your condition, and will be determined by your doctor.

How to take it

Nimotop tablets:

Swallow the tablets whole with a full glass of water.

Nimotop infusion solution:

This should only be administered by a doctor or nurse.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

If you forget to take it

Nimotop tablets:

Please consult your doctor.

If you miss one or more doses of Nimotop tablets, DO NOT TAKE A DOUBLE DOSE. The next dose should be taken as close as possible to the usual dosage time, either the last dose missed or the next dose, whichever is sooner.

Alternately, you may begin a new dosage schedule, maintaining an interval of 4 hours between doses.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre for advice (telephone in Australia 13 11 26; in New Zealand 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Nimotop. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of an overdose include flushing, headache, faintness or dizziness from dramatic drop in blood pressure, irregular heartbeat, nausea and/or other stomach and bowel complaints.

WHILE YOU ARE USING NIMOTOP

Things you must do

If you are about to be started on any new medicine, remind your doctor, nurse or pharmacist that you are taking Nimotop.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests such as blood tests or monitoring your blood pressure from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Nimotop to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Nimotop may cause dizziness or faintness in some patients, especially after the first few doses or when changing medication. Your ability to drive and/or operate machinery may be impaired. If you drink alcohol, dizziness or faintness may be worse.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking Nimotop.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any side effects that worry you.

If any of the following happen, stop taking Nimotop and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, or other parts of the body, shortness of breath, wheezing, or trouble breathing
- irregular heartbeats
- lack of bowel movement, stomach pain or cramping

The above list includes serious side effects. You may need urgent medical attention or hospitalisation.

Your doctor may need to monitor your liver function, blood pressure and conduct blood tests from time to time to check your progress as Nimotop can affect your liver function and blood pressure. You may not experience any specific symptoms.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

accordingly and monitor your condition.

Storage

Nimotop tablets:

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Nimotop infusion solution: Nimotop infusion solution is kept in the pharmacy or ward, in a cool dry place where the temperature stays below 25°C.

Nimotop infusion solution is sensitive to light and should not be exposed to direct sunlight. Infusion tubes and pumps should be protected from light with coverings, or coloured tubing may be used. Indirect sunlight or artificial light does not require the use of such protection.

Nimotop tablets and infusion solution:

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

AFTER USING NIMOTOP

When treatment is to be stopped, your prescribing doctor may need to alter the dose of other medication

PRODUCT DESCRIPTION

What it looks like

Nimotop tablets are round, yellow film-coated tablets, marked with SK on one side and the Bayer cross on the other. The tablets are supplied as blister packs of 100 tablets.

Nimotop IV is a clear slightly yellow solution in a glass vial. There is 50 mL in each vial.

Ingredients

Active ingredient:

- Nimotop tablets – 30 mg of nimodipine per tablet
- Nimotop IV – 10 mg of nimodipine per 50 mL vial

Inactive ingredients (tablet):

- microcrystalline cellulose
- povidone
- maize starch
- magnesium stearate
- crospovidone
- hypromellose
- macrogol 4000
- iron oxide yellow
- titanium dioxide

Inactive ingredients (solution):

- sodium citrate dihydrate
- citric acid
- macrogol 400
- ethanol
- water for injection

Supplier

Made in Germany for:

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
North Shore
Auckland 0627

Australian Registration Numbers

Nimotop - AUST R 43100

Nimotop IV - AUST R 43101

Date of preparation

April 2017

See TGA website
(www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website
(www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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