

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NIMOTOP?

NIMOTOP contains the active ingredient nimodipine. NIMOTOP is 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).

For more information, see Section [1. Why am I using NIMOTOP?](#) in the full CMI.

2. What should I know before I use NIMOTOP?

Do not use if you have ever had an allergic reaction to nimodipine or any of the ingredients listed at the end of the CMI.

NIMOTOP infusion solution contains alcohol. Tell your doctor if you suffer from alcoholism or impaired alcohol metabolism.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NIMOTOP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NIMOTOP and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NIMOTOP?

- Your doctor will decide the appropriate dose for you. Follow all instructions given to you by your doctor and pharmacist.
- A doctor or nurse will prepare and administer the infusion.

More instructions can be found in Section [4. How do I use NIMOTOP?](#) in the full CMI.

5. What should I know while using NIMOTOP?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using NIMOTOP.• Keep all of your doctor's appointments so that your progress can be checked.• Tell your doctor straightaway if you become pregnant while taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• NIMOTOP may cause dizziness or faintness in some patients, especially after the first few doses or when changing medication.
Drinking alcohol	<ul style="list-style-type: none">• If being given NIMOTOP infusion solution, tell your doctor if you drink alcohol. Alcohol may be harmful for those suffering from alcoholism or impaired alcohol metabolism. It may also alter the effects of other medicines.
Looking after your medicine	<ul style="list-style-type: none">• Keep your NIMOTOP tablets in the pack and protected from light until it is time to take them. Refer to the medicine carton for the storage temperature.• NIMOTOP infusion solution is kept in the pharmacy or ward, in a cool dry place below 25°C and protected from light.

For more information, see Section [5. What should I know while using NIMOTOP?](#) in the full CMI.

6. Are there any side effects?

NIMOTOP may cause serious side effects such as allergic reactions (e.g. 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 or gastrointestinal problems such as lack of bowel movements, stomach pain or cramping.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NIMOTOP[®] (NEE·moe·top)

Active ingredient: *nimodipine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NIMOTOP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NIMOTOP.**

Where to find information in this leaflet:

- [1. Why am I using NIMOTOP?](#)
- [2. What should I know before I use NIMOTOP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NIMOTOP?](#)
- [5. What should I know while using NIMOTOP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NIMOTOP?

NIMOTOP tablets and infusion solution contain the active ingredient nimodipine. NIMOTOP 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.

NIMOTOP is 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).

2. What should I know before I use NIMOTOP?

Warnings

Do not use NIMOTOP if:

- you are allergic to nimodipine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- have any other medical conditions, including:
 - low blood pressure
 - heart conditions
 - fluid retention in the brain

- kidney or liver disease
- bowel obstruction
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with NIMOTOP and affect how it works.

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.

Foods that may increase the effect of NIMOTOP:

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NIMOTOP.

4. How do I use NIMOTOP?

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.
- 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.

When to take NIMOTOP

NIMOTOP tablets

- **NIMOTOP tablets should be taken at about the same times 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.

NIMOTOP infusion solution

- NIMOTOP infusion solution should be given as directed 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.

If you forget to take NIMOTOP

NIMOTOP tablets

NIMOTOP should be used regularly at the same time each day. If you miss your dose at the usual time, 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.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

Alternately, you may begin a new dosage schedule, maintaining an interval of 4 hours between doses. Check with your doctor if you are unsure how to do this.

NIMOTOP infusion solution

NIMOTOP infusion solution is administered by a doctor or nurse in a hospital. If you miss your dose at the usual time, tell your doctor.

If you use too much NIMOTOP

If you think that you have used too much NIMOTOP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 POISON or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using NIMOTOP?

Things you should do

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

Call your doctor straight away if you:

- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are using NIMOTOP.

Things you should not do

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NIMOTOP affects you.

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.

Drinking alcohol

If taking NIMOTOP infusion solution, tell your doctor if you drink alcohol.

Alcohol may be harmful for those suffering from alcoholism or impaired alcohol metabolism. It may also alter the effects of other medicines.

Looking after your medicine

NIMOTOP tablets:

- Keep your tablets in the pack and protected from light until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Refer to the medicine carton for the storage temperature.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

NIMOTOP infusion solution:

NIMOTOP infusion solution is kept in the pharmacy or ward, in a cool dry place 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.

Getting rid of any unwanted medicine

If you no longer need to use NIMOTOP tablets or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Any unwanted NIMOTOP infusion solution will be disposed of in a safe manner by your doctor, nurse or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
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<p>Allergic reaction:</p> <ul style="list-style-type: none"> • 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 <p>Heart-related:</p> <ul style="list-style-type: none"> • irregular heartbeats <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> • lack of bowel movement • stomach pain or cramping 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NIMOTOP contains

NIMOTOP tablets:

Active ingredient (main ingredient)	30 mg of nimodipine per tablet
Other ingredients (inactive ingredients)	microcrystalline cellulose, povidone, maize starch, magnesium stearate, crospovidone, hypromellose, macrogol 4000, iron oxide yellow and titanium dioxide
Potential allergens	N/A

NIMOTOP infusion solution:

Active ingredient (main ingredient)	10 mg of nimodipine per 50 mL vial
Other ingredients (inactive ingredients)	sodium citrate dihydrate, citric acid, macrogol 400, ethanol, water for injections
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What NIMOTOP 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 (Aust R 43100).

NIMOTOP infusion solution is a clear slightly yellow solution in a glass vial. There is 50 mL in each vial. There are 5 vials in each carton. (Aust R 43101).

Who distributes NIMOTOP

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

Bayer New Zealand Limited
B:Hive Building
72 Taharoto Road, Takapuna Auckland 0622

This leaflet was prepared in August 2023.

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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