PART III: CONSUMER INFORMATION

PrNIMOTOP® Tablets

nimodipine tablets Bayer Standard

This leaflet is Part 3 of a three-part "Product Monograph" published when NIMOTOP Tablets was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NIMOTOP Tablets. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

NIMOTOP Tablets are used for the treatment subarachnoid hemorrhage (medical term for bleeding inside the head) and help to prevent brain damage that may result from the bleeding.

What it does:

Following subarachnoid hemorrhage (medical term for bleeding inside the head), the blood vessels may go into spasm. This may result in inadequate circulation in the affected areas of the brain and thus damage the nervous system. NIMOTOP Tablets are used to prevent and, if necessary, to treat such damage.

When it should not be used:

Do not take NIMOTOP Tablets:

- if you have suffered from a head injury resulting in a traumatic subarachnoid hemorrhage
- during or within one month of a heart attack
- if you suffer from angina and notice an increase in the frequency and severity of attacks
- if you are taking the antibiotic rifampin or the antiepileptics phenobarbital, phenytoin or carbamazepine as the effect of NIMOTOP Tablets may be reduced
- if you are breastfeeding
- if you are allergic (hypersensitive) to nimodipine or to any of the ingredients in this product. The ingredients are listed in the **"What the nonmedicinal ingredients are"** section of this leaflet

What the medicinal ingredient is:

The active substance is nimodipine

What the nonmedicinal ingredients are:

Crospovidone, ferric oxide yellow, hypromellose, macrogol, magnesium stearate, maize starch, microcrystalline cellulose, povidone, and titanium dioxide

What dosage forms it comes in:

Film-coated tablets, 30 mg

WARNINGS AND PRECAUTIONS

BEFORE you use NIMOTOP Tablets, talk to your doctor or pharmacist if you have or have had any of the following conditions:

- have hypotension (systolic blood pressure below 100 mmHg)
- have been told that you have cerebral edema or severely raised intracranial pressure
- have a history of liver disease
- have a history of heart disease
- may be pregnant or are breastfeeding

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with NIMOTOP Tablets include:

- drugs used for the treatment of epilepsy (eg, phenytoin, carbamazepine, phenobarbital, valproic acid); tuberculosis (eg, rifampin) and HIV infections (eg, ritonavir)
- antibiotics (eg, erythromycin) for infectious disease
- antihypertensive drugs (for high blood pressure), including other calcium channel blockers
- drugs used to treat fungal infections (eg, ketoconazole), unless they are applied only to the skin
- antidepressants (eg, fluoxetine, nortriptyline)
- drugs used to treat indigestion (eg, cimetidine)
- herbal remedy St. John's Wort (primarily used for the treatment of depressive moods)

If you are taking any of the above drugs, remind your doctor before taking NIMOTOP tablets. If necessary, a reduction in the nimodipine dose should be considered.

NIMOTOP Tablets should not be taken at the same time as grapefruit juice, or near the time of eating grapefruit. This is because grapefruit juice is known to increase the blood levels of the active ingredient, nimodipine.

This is not a complete list of possible drug interactions with NIMOTOP Tablets. Talk to your doctor for more information about drug interactions.

See also **ABOUT THIS MEDICATION: When it should not be used**, and **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**.

PROPER USE OF THIS MEDICATION

Usual dose

For the management of neurological deficits following subarachnoid hemorrhage (SAH), therapy with NIMOTOP Tablets should start as soon as possible or within 4 days of the diagnosis of SAH.

The recommended dosage of NIMOTOP Tablets is 60 mg (two tablets of 30 mg) administered orally every 4 hours for 21 consecutive days after diagnosis of SAH. Doses up to 90 mg every 4 hours have been used in some patients, although the safety of higher doses in severely ill patients has not been well established.

The tablets should be swallowed whole with plenty of fluid (preferably a glass of water), independently of meal times. Grapefruit juice should be avoided. It is recommended that the tablets are not taken while lying down.

Children and Adolescents

Do not give NIMOTOP Tablets to patients under 18 years of age. There is not enough information on their use in children and adolescents.

Pregnancy and Breastfeeding

If you are pregnant or are planning a family, tell your doctor before taking NIMOTOP Tablets. Investigations have not been carried out into the damaging effects of NIMOTOP during pregnancy. NIMOTOP should therefore only be taken during pregnancy after careful consideration of the benefits and potential risks arising from the severity of the clinical situation.

Since nimodipine (the active ingredient in NIMOTOP Tablets) may pass into breast milk, breastfeeding should be discontinued while taking this drug.

Overdose

Symptoms of acute overdosage to be anticipated are marked lowering of the blood pressure, an irregular heart beat, flushing, headache, digestive upset and nausea.

In the event of acute overdose, discontinue use of NIMOTOP Tablets immediately and contact your doctor or your regional Poison Control Centre immediately.

Missed Dose

If you have forgotten to take a dose, take it as soon as you remember. Carry on with the remaining tablets at the normal four-hour intervals.

Do not take a double dose to make up for a forgotten tablet.

Stopped Treatment

You should always consult your doctor before deciding to interrupt or stop the course of NIMOTOP Tablet treatment (eg, on account of side effects) since NIMOTOP Tablets prevent the development of serious neurological deficits.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, NIMOTOP can cause side effects, although not everybody gets them.

The most common side effects seen with NIMOTOP are allergic reaction (eg, rash), decreased blood pressure, irregular heartbeat, headache, sweating, flushing, nausea.

There is a possibility that you may feel dizzy; if you are affected you should not drive or operate machinery.

Please inform your doctor or pharmacist if you experience any side effects. If necessary, your doctor may reduce or stop treatment with NIMOTOP Tablets.

You should be aware that prescription medications carry some risks and that all possible risks may not be known at this stage.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical treatment
		Only if severe	In all cases	
Common	Low blood pressure (lightheaded-ness, dizziness, and/or fainting)			✓
	Allergic reactions: difficulty breathing or swallowing, rash or hives (redness, intense itching), swelling of face, throat, tongue, lips, eyes, hands, feet, ankles, lower legs)			✓
	Localized swelling, swelling in your limbs		✓	
	Increased frequency and looseness in bowel movement		✓	
	Unease and discomfort in the stomach with an urge to vomit		✓	
Uncommon	Headache, pain in the neck and/or upper back			✓
	Yellowing of the skin or eyes (jaundice)			✓
	Anemia (exceptional weakness, paleness, dizziness, headache)		✓	

This is not a complete list of side effects. For any unexpected effects while taking NIMOTOP Tablets, contact your doctor or pharmacist.

HOW TO STORE IT

NIMOTOP tablets should be stored in the original packaging between 15°C and 30°C. Protect from humidity.

Keep out of reach of children.

Medications should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medications you no longer require. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program:

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:
    Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at: http://www.bayer.ca or by contacting the manufacturer at the above-mentioned phone number and e-mail address.

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