



# NIMOTOP®

## Film Coated Tablet

Important information, please read carefully!

### Composition

1 film-coated tablet contains 30 mg nimodipine.

Yellow film-coated tablet, round biconvex, diameter 10 mm, radius of curvature 15mm, weight 339 mg, tablet code side-SK, other side Bayer Cross.

### Properties

#### PHARMACODYNAMIC PROPERTIES

Nimodipine has a predilective cerebral antivasoconstrictive and antiischaemic activity. Vasoconstrictions provoked in vitro by various vasoactive substances (e.g. serotonin, prostaglandins, and histamine) or by blood and blood degradation products can be prevented or eliminated by nimodipine.

Nimodipine also has neuropharmacological and psychopharmacological properties.

Investigations in patients with acute cerebral blood flow disturbances have shown that nimodipine dilates the cerebral blood vessels and promotes cerebral blood flow.

The increase in perfusion is as a rule greater in previously damaged or underperfused brain region than in healthy regions.

The ischaemic neurological damage in patients with subarachnoid haemorrhage and the mortality rate are significantly reduced by nimodipine.

#### PHARMACOKINETIC PROPERTIES

##### Absorption

The orally administered active substance nimodipine is practically completely absorbed.

The peak plasma concentration and the area under the curve increase proportionally to the dose up to the highest dose under test (90 mg).

The distribution volume ( $V_{ss}$ , 2-compartment model) for i.v. administration is calculated to be 0.9 - 1.6 l/kg body weight.

The total (systemic) clearance is 0.6 - 1.9 l/h/kg.

##### Protein binding and distribution

Nimodipine is 97 - 99 % bound to plasma proteins.

##### Metabolism, elimination and excretion

Nimodipine is eliminated metabolically via the cytochrome P450 3A4 system,

##### Bioavailability

Attributed to the extensive first-pass metabolism (about 85 - 95 %) the absolute bioavailability is 5 - 15 %.

### Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity, genotoxicity, carcinogenicity and male and female fertility. In pregnant rats, doses of 30 mg/kg/day and higher inhibited foetal growth and resulted in reduced foetal weights. At 100 mg/kg/day embryoletality occurred. No evidence of teratogenicity was observed. In rabbits, no embryotoxicity and teratogenicity occurred at doses up to 10 mg/kg/day. In one peri-postnatal study in rats, mortality and delayed physical development were observed at doses of 10 mg/kg/day and higher. The findings were not confirmed in subsequent studies.

### Therapeutic indications

For prophylaxis and treatment of ischaemic neurological deficits caused by cerebral vasospasm following subarachnoid haemorrhage of aneurysmal origin.

### Dosage and method of administration

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**Dosage:**

Unless otherwise prescribed, the following dose guidelines are recommended.

The recommended procedure is administration of Nimotop infusion solution for 5 - 14 days, followed by a daily dose of 6 x 2 Nimotop tablets (6 x 60 mg nimodipine).

In patients who develop adverse reactions the dose should be reduced as necessary or the treatment discontinued.

**Patients with hepatic impairment**

Severely disturbed liver function, particularly liver cirrhosis, may result in an increased bioavailability of nimodipine due to a decreased first-pass capacity and a reduced metabolic clearance.

The effects and side-effects, e.g. reduction in blood-pressure, may be more pronounced in these patients.

In such cases the dose should be reduced, depending on the blood pressure; or, if necessary, discontinuation of the treatment should be considered.

Upon co-administration with CYP 3A4 inhibitors or CYP 3A4 inducers a dose-adaptation may be necessary (see "Interaction with other medicinal products and other forms of interaction").

**Administration**

Administration of Nimotop tablets is recommended for about 7 days after the end of 5-14 days infusion therapy with Nimotop infusion solution.

In general, the tablets should be swallowed in whole with a little liquid, independent of meal time.

Grapefruit juice is to be avoided (see "Interaction with other medicinal products and other forms of interaction").

The interval between successive doses must not be less than 4 h.

**Duration of use****Prophylactic Use**

After the end of the infusion therapy, it is advisable to continue with oral administration of 6 x 60 mg nimodipine daily at four-hourly intervals for about a further 7 days.

**Therapeutic Use**

After intravenous application, oral administration of 6 x 60 mg nimodipine per day at four-hourly intervals for 7 days is recommended.

**Contraindications**

Nimotop tablets must not be used in cases of hypersensitivity to nimodipine or to any of the excipients.

The use of nimodipine in combination with rifampicin is contraindicated as efficacy of Nimotop tablets could be significantly reduced when concomitantly administered with rifampicin. (see "Interaction with other medicinal products and other forms of interaction").

The concomitant use of oral nimodipine and the antiepileptic drugs phenobarbital, phenytoin or carbamazepine is contraindicated as efficacy of Nimotop tablets could be significantly reduced (see "Interaction with other medicinal products and other forms of interaction").

**Special warnings and special precautions for use**

Although treatment with Nimotop has not been shown to be associated with increases in intracranial pressure, close monitoring is recommended in these cases or when the water content of the brain tissue is elevated (generalized cerebral oedema).

Caution is required in markedly hypotensive patients (systolic blood pressure < 100 mm Hg).

In patients with unstable angina or within the first 4 weeks after acute myocardial infarction, physicians should consider the potential risk (e.g. reduced coronary artery perfusion and myocardial ischemia) versus the benefit (e.g. improvement of brain perfusion).

Nimodipine is metabolized via the cytochrome P450 3A4 system. Drugs that are known to either inhibit or to induce this enzyme system may therefore alter the first pass or the clearance of nimodipine (see "Interaction with other medicinal products and other forms of interaction").

Drugs, which are known inhibitors of the cytochrome P450 3A4 system and therefore may lead to increased plasma concentrations of nimodipine are, e.g.:

- macrolide antibiotics (e.g., erythromycin),
- anti-HIV protease inhibitors (e.g., ritonavir),
- azole antimycotics (e.g., ketoconazole),
- the antidepressants nefazodone and fluoxetine
- quinupristin/dalfopristin,
- cimetidine,
- valproic acid.

Upon co-administration with these drugs, the blood pressure should be monitored and, if necessary, a reduction of the nimodipine dose should be considered.

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## Interaction with other medicinal products and other forms of interaction

### Drugs that affect nimodipine:

Nimodipine is metabolised via the cytochrome P450 3A4 system, located both in the intestinal mucosa and in the liver. Drugs that are known to either inhibit or to induce this enzyme system may therefore alter the first pass or the clearance of nimodipine.

The extent as well the duration of interactions should be taken into account when administering nimodipine together with the following drugs:

### Rifampicin

From the experience with other calcium antagonists it has to be expected that rifampicin accelerates the metabolism of nimodipine due to enzyme induction. Thus, efficacy of nimodipine could be significantly reduced when concomitantly administered with rifampicin. The use of nimodipine in combination with rifampicin is therefore contraindicated (see "Contraindications").

### Cytochrome P450 3A4 system-inducing anti-epileptic drugs, such as phenobarbital, phenytoin or Carbamazepine

Previous chronic administration of the antiepileptic drugs phenobarbital, phenytoin or carbamazepine markedly reduces the bioavailability of orally administered nimodipine. Therefore, the concomitant use of oral nimodipine and these antiepileptic drugs is contraindicated (see "Contraindications").

Upon co-administration with the following inhibitors of the cytochrome P450 3A4 system the blood pressure should be monitored and, if necessary, an adaptation in the nimodipine dose should be considered (see "Posology and method of administration").

### Macrolid antibiotics (e.g., erythromycin)

No interaction studies have been carried out between nimodipine and macrolid antibiotics. Certain macrolid antibiotics are known to inhibit the cytochrome P450 3A4 system and the potential for drug interaction cannot be ruled out at this stage. Therefore, macrolide antibiotics should not be used in combination with nimodipine (see "Special warnings and precautions for use"). Azithromycin, although structurally related to the class of macrolid antibiotic is void of CYP3A4 inhibition.

### Anti-HIV protease inhibitors (e.g., ritonavir)

No formal studies have been performed to investigate the potential interaction between nimodipine and anti-HIV protease inhibitors. Drugs of this class have been reported to be potent inhibitors of the cytochrome P450 3A4 system. Therefore, the potential for a marked and clinically relevant increase in nimodipine plasma concentrations upon co-administration with these protease inhibitors cannot be excluded (see "Special warnings and precautions for use").

### Azole anti-mycotics (e.g., ketoconazole)

A formal interaction study investigating the potential of drug interaction between nimodipine and ketoconazole has not been performed. Azole anti-mycotics are known to inhibit the cytochrome P450 3A4 system, and various interactions have been reported for other dihydropyridine calcium antagonists. Therefore, when administered together with oral nimodipine, a substantial increase in systemic bioavailability of nimodipine due to a decreased first-pass metabolism cannot be excluded (see "Special warnings and precautions for use").

### Nefazodone

No formal studies have been performed to investigate the potential interaction between nimodipine and nefazodone. This antidepressant drug has been reported to be a potent inhibitor of the cytochrome P450 3A4. Therefore, the potential for an increase in nimodipine plasma concentrations upon co-administration with nefazodone cannot be excluded (see "Special warnings and precautions for use").

### Fluoxetine

The steady-state concomitant administration of nimodipine with the antidepressant fluoxetine led to about 50% higher nimodipine plasma concentrations. Fluoxetine exposure was markedly decreased, while its active metabolite norfluoxetine was not affected.

### Quinupristin/dalfopristin

Based on experience with the calcium-antagonist nifedipine, co-administration of quinupristin/dalfopristin may lead to increased plasma concentrations of nimodipine (see "Special warnings and precautions for use").

### Cimetidine

The simultaneous administration of the H<sub>2</sub>-antagonist cimetidine can lead to an increase in the plasma nimodipine concentration (see "Special warnings and precautions for use").

### Valproic acid

The simultaneous administration of the anticonvulsant valproic acid can lead to an increase in the plasma nimodipine concentration (see "Special warnings and precautions for use").

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### **Further drug interactions:**

#### **Nortriptyline**

The steady-state concomitant administration of nimodipine and nortriptyline led to a slight decrease in nimodipine exposure with unaffected nortriptyline plasma concentrations.

### **Effects of nimodipine on other drugs:**

Blood pressure lowering drugs

Nimodipine may increase the blood pressure lowering effect of concomitantly applied anti-hypertensives, such as:

- diuretics,
- $\beta$ -blockers,
- ACE inhibitors,
- A1-antagonists,
- other calcium antagonists,
- $\alpha$ -adrenergic blocking agents,
- PDE5 inhibitors,
- $\alpha$ -methyl dopa.

However, if a combination of this type proves unavoidable particularly careful monitoring of the patient is necessary.

### **Zidovudine**

In a monkey study simultaneous administration of anti-HIV drug zidovudine i.v. and nimodipine bolus i.v. resulted for zidovudine in significantly higher AUC, whereas the distribution volume and clearance were significantly reduced.

### **Drug-food interactions:**

Grapefruit juice

Grapefruit juice inhibits the cytochrome P450 3A4 system. Administration of dihydropyridine calcium antagonists together with grapefruit juice thus results in elevated plasma concentrations and prolonged action of nimodipine due to a decreased first pass metabolism or reduced clearance.

As a consequence, the blood pressure lowering effect may be increased. After intake of grapefruit juice this effect may last for at least 4 days after the last ingestion of grapefruit juice. Ingestion of grapefruit / grapefruit juice is therefore to be avoided while taking nimodipine (see "Posology and method for administration").

## **Pregnancy & Lactation**

### **Pregnancy:**

There are no adequate and well controlled studies in pregnant women. If nimodipine is to be administered during pregnancy, the benefits and the potential risks must therefore be carefully weighed according to the severity of the clinical picture.

### **Lactation:**

Nimodipine and its metabolites have been shown to appear in human milk at concentrations of the same order of magnitude as corresponding maternal plasma concentrations. Nursing mothers are advised not to breastfeed their babies when taking the drug.

### **In-vitro fertilization**

In single cases of in-vitro fertilization calcium antagonists have been associated with reversible biochemical changes in the spermatozoa's head section that may result in impaired sperm function.

## **Effects on ability to drive and use machines**

In principle the ability to drive and use machines can be impaired in connection with the possible occurrence of dizziness.

## **Undesirable effects**

Adverse drug reactions (ADRs) based on clinical trials with nimodipine in the indication aSAH sorted by CIOMS III categories of frequency (placebo-controlled studies nimodipine N = 703; placebo N = 692; uncontrolled studies: nimodipine N = 2496; status: 31 Aug 2005) are listed below:

The frequencies of ADRs reported with nimodipine are summarized in the table below. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Frequencies are defined as:

very common ( $\geq 1/10$ ),

common ( $\geq 1/100$  to  $< 1/10$ ),

uncommon ( $\geq 1/1,000$  to  $< 1/100$ ),

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rare ( $\geq 1/10,000$  to  $< 1/1,000$ ),  
very rare ( $< 1/10,000$ ).

**Table 01: ADR table**

<u>System Organ Class (MedDRA)</u>	<u>Uncommon</u>	<u>Rare</u>
<u>Blood and the lymphatic system disorders</u>	<u>Thrombocytopenia</u>	
<u>Immune system disorders</u>	<u>Allergic reaction</u> <u>Rash</u>	
<u>Nervous system disorders</u>	<u>Headache</u>	
<u>Cardiac disorders</u>	<u>Tachycardia</u>	<u>Bradycardia</u>
<u>Vascular disorders</u>	<u>Hypotension</u> <u>Vasodilatation</u>	
<u>Gastrointestinal disorders</u>	<u>Nausea</u>	<u>Ileus</u>
<u>Hepato-biliary disorders</u>		<u>Transient increase in liver enzymes</u>

#### Reporting of Suspected adverse drug reaction

Reporting suspected adverse reaction after product authorization is crucial for on-going benefit-risk monitoring. Healthcare professionals are requested to report any suspected adverse reactions to PT Bayer Indonesia through email at [drugsafety@bayer.com](mailto:drugsafety@bayer.com).

#### Overdose

##### Symptoms of intoxication:

Symptoms of acute overdosage to be anticipated are marked lowering of the blood pressure, tachycardia or bradycardia, and gastrointestinal complaints and nausea.

##### Treatment of intoxication

In the event of acute overdosage treatment with Nimotop tablet must be discontinued immediately.

Emergency measures should be governed by the symptoms.

If the substance was ingested orally, gastric lavage with addition of charcoal should be considered as an emergency therapeutic measure.

If there is a marked fall in blood pressure, dopamine or nor-adrenaline can be administered intravenously.

Since no specific antidote is known, subsequent treatment for other side effects should be aimed at the most prominent symptoms.

#### Presentation

Box, 5 strips @ 10 film-coated tablets

#### Excipients

Microcrystalline cellulose, Povidone, Maize starch, Crospovidone, Magnesium stearate, Hypromellose, Macrogol 4000, Titanium dioxide and Iron oxide yellow.

#### Instruction for use/handling:

##### Storage

Store below 30°C

Nimotop® film-coated tablet must not be used after the expiry date

Keep the drug out of reach of children

**Harus dengan resep dokter**

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Reg. No. **XXXXXXXXXXXXXXXXXX**

**Made by Bayer AG, Leverkusen – Germany  
Imported by PT Bayer Indonesia, Depok – Indonesia  
Packed by PT Actavis Indonesia, Jakarta – Indonesia**

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## LEMBAR INFORMASI UNTUK PASIEN

### Tablet Nimotop® 30 mg

Nimodipin

**Bacalah seluruh isi brosur ini dengan saksama sebelum Anda mulai mengonsumsi obat karena terdapat informasi yang penting bagi Anda.**

- Simpan brosur ini. Anda mungkin memerlukannya nanti.
- Jika ada pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini telah diresepkan khusus untuk Anda. Jangan berikan kepada orang lain. Hal ini dapat membahayakan mereka meskipun mereka memiliki gejala penyakit yang sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter atau apoteker. Termasuk juga kemungkinan efek samping yang tidak tercantum dalam brosur ini.

#### Isi brosur ini

1. Penjelasan tentang tablet Nimotop dan kegunaannya
2. Hal yang perlu diketahui sebelum mengonsumsi tablet Nimotop
3. Cara mengonsumsi tablet Nimotop
4. Kemungkinan efek samping
5. Cara menyimpan tablet Nimotop
6. Isi kemasan dan informasi lainnya

#### 1. Penjelasan tentang tablet Nimotop dan kegunaannya

Nimotop tablet adalah obat yang mengandung Nimodipine 30 mg. Nimotop digunakan untuk mencegah dan mengobati defisit neurologis (fungsi neurologis yang menurun/tidak normal) akibat vasospasme (penyempitan pembuluh darah) setelah terjadinya perdarahan subaraknoid yang berasal dari aneurisma (penonjolan pada dinding pembuluh darah).

#### 2. Hal yang perlu diketahui sebelum mengonsumsi tablet Nimotop

##### Jangan konsumsi tablet Nimotop:

- **Pada waktu yang sama saat Anda sedang diinfus dengan larutan infus Nimotop.** Tablet telah diresepkan sebagai metode yang lebih praktis untuk melanjutkan pengobatan setelah infus dihentikan.
- **Jika Anda mengalami serangan jantung** dalam sebulan terakhir.
- **Jika Anda alergi terhadap nimodipin** atau bahan lain yang terkandung dalam obat ini (tercantum dalam bagian 6).
- **Jika Anda sedang mengonsumsi rifampisin** (antibiotik), **fenobarbital, fenitoin, atau karbamazepin** (tiga obat yang paling umum digunakan dalam pengobatan epilepsi).

**Beri tahu Dokter dan jangan konsumsi tablet Nimotop** jika salah satu kondisi tersebut berlaku bagi Anda.

#### Peringatan dan tindakan pencegahan

Konsultasikan dengan dokter atau apoteker sebelum mengonsumsi tablet Nimotop:

- **Jika terdapat cairan dalam otak Anda atau terjadi peningkatan tekanan yang parah dalam tengkorak Anda.** Dokter akan dapat memberikan saran lebih lanjut kepada Anda.
- **Jika Anda menderita tekanan darah rendah.** Tekanan darah Anda mungkin perlu diperiksa secara rutin.
- **Jika Anda menderita penyakit hati.**
- **Jika anda mengalami nyeri dada yang tidak stabil** atau dalam 4 minggu pertama setelah serangan jantung akut. Dokter harus mempertimbangkan potensi risiko (misalnya aliran darah ke jantung bisa

berkurang sehingga menyebabkan menurunnya fungsi jantung) lebih besar daripada manfaatnya (misalnya peningkatan aliran darah ke otak bisa lebih lancar).

**Beri tahu dokter sebelum mengonsumsi tablet Nimotop** jika salah satu kondisi tersebut berlaku bagi Anda.

#### **Interaksi tablet Nimotop dengan obat-obatan lain**

**Anda tidak boleh diresepkan rifampisin** (antibiotik), **fenobarbital**, **fenitoin**, atau **karbamazepin** (obat antiepilepsi) jika Anda sedang mengonsumsi tablet Nimotop.

**Beri tahu dokter** jika Anda sedang mengonsumsi, baru-baru ini mengonsumsi, atau mungkin akan mengonsumsi obat apa pun lainnya. Beberapa obat dapat memengaruhi cara kerja Nimotop.

**Beri tahu dokter** jika Anda sedang mengonsumsi:

- **Tablet untuk tekanan darah tinggi** termasuk golongan obat antidiuretik, beta bloker, ACE inhibitor, antagonis reseptor angiotensin I, antagonis kalsium lainnya, alfa-adrenergic bloker, penghambat PDE5, dan alfa-metildopa. Penggunaan Nimotop tablet dapat meningkatkan efek obat-obatan tersebut.
- Obat **antitukak lambung** bernama **simetidin** atau obat **antiepilepsi** bernama **natrium valproat**. Obat-obatan ini dapat meningkatkan khasiat tablet Nimotop.
- Obat antidepresan fluoksetin atau nefazodon.
- Obat **anti-HIV zidovudin** (seperti AZT)
- **Obat penghambat protease HIV** (seperti ritonavir)
- Antibiotik eritromisin atau obat antijamur seperti ketokonazol
- Obat antibiotik kombinasi seperti kuinupristin/dalfopristin.
- **Nortriptilin**: pemberian nimodipin dan nortriptilin secara bersamaan dalam kondisi steady state (konstan) menyebabkan sedikit penurunan paparan nimodipin, namun tidak memengaruhi konsentrasi plasma nortriptilin.

#### **Interaksi tablet Nimotop dengan makanan dan minuman**

Anda dapat mengonsumsi tablet Nimotop dengan perut kosong atau setelah makan.

**Jangan mengonsumsi tablet Nimotop bersama dengan buah grapefruit atau sari buahnya.**

Jangan mulai mengonsumsi tablet Nimotop sebelum lewat 4 hari setelah konsumsi buah grapefruit atau sari buahnya. Beri tahu dokter jika Anda mengonsumsi buah grapefruit atau sari buahnya dalam 4 hari terakhir.

Selain itu, jangan mengonsumsi tablet Nimotop bersama dengan buah grapefruit atau sari buahnya. Efeknya dapat bertahan selama setidaknya empat hari.

#### **Kehamilan, menyusui, dan kesuburan**

**Jika Anda sedang hamil**, menduga bahwa Anda mungkin hamil, atau berencana hamil, konsultasikan dengan dokter sebelum mengonsumsi obat ini. Ikuti instruksi dokter dengan saksama.

**Jangan menyusui** selama mengonsumsi tablet Nimotop.

**Jika Anda adalah pria yang sedang mengikuti program untuk mempunyai keturunan**, konsultasikan hal ini dengan dokter. Obat seperti tablet Nimotop kadang dapat berdampak pada kesuburan pria.

#### **Mengemudi dan mengoperasikan mesin**

Tablet Nimotop dapat menyebabkan pusing. Jangan mengemudi atau mengoperasikan mesin jika Anda mengalami efek samping ini.

### 3. Cara mengonsumsi tablet Nimotop

Selalu konsumsi obat ini sesuai dengan dosis yang diinformasikan oleh dokter. Tanyakan kepada dokter atau apoteker jika Anda ragu.

- **Dosis yang dianjurkan** adalah 2 tablet setiap empat jam. Artinya, dosis maksimum dalam sehari adalah 12 tablet (360 mg).
- Nimotop tablet dianjurkan dikonsumsi selama 7 hari setelah selesai terapi infus Nimotop yang berlangsung 5–14 hari.
- Tablet harus ditelan utuh dengan sedikit air, tidak tergantung pada waktu makan.
- Tetaplah mengonsumsi tablet sesuai dengan durasi yang diinformasikan oleh dokter.

#### **Jangan mengonsumsi obat ini melebihi dosis yang diresepkan dokter.**

Jika Anda mengonsumsi tablet Nimotop melebihi dosis yang disarankan segera cari pertolongan medis dan, jika memungkinkan, bawalah tablet yang Anda konsumsi. Konsumsi tablet Nimotop yang melebihi dosis dapat menyebabkan tekanan darah rendah (Anda mungkin merasa lemas), jantung berdetak lebih cepat atau lebih lambat daripada biasanya, dan mual.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker.

### 4. Kemungkinan efek samping

Seperti obat pada umumnya, obat ini dapat menimbulkan efek samping pada sebagian orang.

#### **Kemungkinan efek samping serius**

**Jika Anda mengalami:**

- tanda-tanda reaksi alergi, seperti ruam
- tekanan darah rendah (dapat menyebabkan pusing)
- detak jantung lambat
- lebih mudah memar dan berdarah akibat penurunan jumlah keping darah (trombosit)

**Segera hubungi dokter karena efek samping tersebut kadang bisa merupakan kondisi yang serius.**

#### **Efek samping yang lebih ringan**

Selain efek samping serius yang tercantum di atas, berikut adalah efek samping yang lebih ringan dari tablet Nimotop:

#### **Efek samping yang jarang terjadi**

*(Mungkin dialami oleh kurang dari 1 di antara 100 orang)*

- reaksi alergi
- trombositopenia

- vasodilatasi
- hipotensi
- ruam
- sakit kepala
- detak jantung cepat
- ingin muntah (*mual*)

### **Efek samping langka**

(Mungkin dialami oleh kurang dari 1 di antara 1.000 orang)

- detak jantung lambat
- sembelit (buang air besar tidak lancar)
- sedikit peningkatan pada enzim hati (akan terlihat dalam tes darah)

### **Pelaporan dugaan efek samping obat**

Jika mengalami efek samping selama dan/atau setelah penggunaan obat, segera konsultasikan ke dokter atau tenaga kesehatan lainnya.

Untuk pelaporan efek samping, silakan email ke [drugsafety.indonesia@bayer.com](mailto:drugsafety.indonesia@bayer.com). Informasi yang disampaikan sangat penting untuk pemantauan manfaat-risiko produk yang berkelanjutan.

### **5. Cara menyimpan tablet Nimotop**

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan disimpan pada suhu lebih dari 30 °C.

Jangan konsumsi obat ini setelah melewati tanggal kedaluwarsa yang tercantum di kemasan.

### **6. Isi kemasan dan informasi lainnya**

#### **Kandungan tablet Nimotop**

Zat aktif obat ini adalah nimodipin. Setiap tablet salut selaput mengandung 30 mg nimodipin.

Bahan lainnya antara lain selulosa mikrokristalina, hipromelosa, makrogol, maizena, povidon, krospovidon, magnesium stearat, dan pewarna titanium dioksida (E171) serta besi oksida kuning (E172).

#### **Bentuk dan isi kemasan tablet Nimotop**

- Tablet Nimotop adalah tablet salut selaput. Tablet ini berwarna kuning, berbentuk bulat, dan cembung di kedua sisinya. Terdapat tanda "SK" di satu sisi dan tanda palang "Bayer" di sisi lainnya.
- Nimotop tersedia dalam kemasan yang berisi dus, 5 strip @ 10 tablet salut selaput.

No. Reg.: DKL1802009517A1

Harus dengan resep dokter

#### **Diproduksi oleh:**

Bayer AG,  
Leverkusen – Germany

**Diimpur oleh :**  
PT Bayer Indonesia  
Depok – Indonesia

**Dikemas oleh:**  
PT Actavis Indonesia  
Jakarta - Indonesia