

APAKAH YANG ADA PADA RISALAH INI

Risalah ini menjawab soalan-soalan umum mengenai *Nimodipine*. Ia tidak mengandungi semua maklumat mengenai ubat ini. Risalah ini hanyalah sebagai rujukan, ia tidak menggantikan nasihat daripada doktor atau ahli farmasi. Sila baca dan fahami seluruh kandungan risalah ini sebelum anda mula mengambil ubat anda. Ubat ini adalah untuk anda, jangan memberikannya kepada orang lain walaupun mereka mempunyai simptom yang sama seperti anda. Jika anda mempunyai sebarang persoalan mengenai ubat ini, sila tanya doktor atau ahli farmasi anda. Simpan risalah ini, anda mungkin perlu membacanya lagi

1. APAKAH KEGUNAAN *Nimodipine*

Nimodipine digunakan untuk mencegah atau merawat kekurangan bekalan darah ke otak yang disebabkan oleh pengecilan salur darah selepas pendarahan di dalam otak.

2. BAGAIMANA *Nimodipine* BERFUNGSI

Nimodipine tergolong dalam kumpulan ubat 'calcium channel blockers', ia berfungsi dengan melebarkan salur darah kecil dalam otak untuk menambah pengaliran darah, menurunkan tekanan darah dan melancarkan peredaran darah.

3. SEBELUM ANDA MENGAMBIL *Nimodipine*

Jangan mengambil ubat ini sekiranya

- Anda mempunyai alahan terhadap bahan aktif atau bahan lain dalam formulasi ini atau ubat lain yang sama.
- Anda mengalami serangan jantung baru-baru ini.
- Anda mengalami sakit dada (angina) baru-baru ini

Sekiranya anda tidak pasti sama ada anda perlu mengambil ubat ini, rujuk kepada doktor anda.

Sebelum anda mula mengambil ubat ini

Maklumkan kepada doktor anda sekiranya anda:

- mempunyai alahan terhadap sebarang ubat, makanan, bahan pengawet atau pewarna,
- mengalami masalah hati,
- mengalami masalah ginjal,
- mempunyai tekanan darah rendah,
- mengalami masalah jantung,
- mengalami penakungan cecair dalam otak.

Mengambil ubat lain

Maklumkan kepada doktor atau ahli farmasi anda sekiranya anda mengambil ubat lain, termasuk yang didapatkan tanpa preskripsi.

Keberkesanan ubat-ubat berikut mungkin dipengaruhi oleh *Nimodipine*, anda mungkin perlu mengubah dos anda atau mengambil ubat lain. Doktor dan ahli farmasi anda mempunyai lebih maklumat tentang ubat-ubat yang boleh diambil atau perlu dielakkan semasa mengambil *Nimodipine*.

Maklumkan kepada doktor anda sekiranya anda mengambil:

- Ubat lain untuk menurunkan tekanan darah
- Ubat dari kumpulan ubat yang sama seperti amlodipine dan felodipine
- Cimetidine (untuk ulser)
- Ubat untuk epilepsi (cth: phenobarbital, phenytoin, valproic acid, dan carbamazepine)
- Antibiotik (cth: erythromycin, rifampicin)
- Ubat anti-kulat (cth: ketoconazole, itraconazole dan fluconazole)
- Ubat anti-virus (cth: indinavir, ritonavir, nelfinavir, saquinavir dan zidovudine),
- Jus limau gedang

Semasa mengandung dan menyusu bayi

Keselamatan penggunaan *Nimodipine* semasa hamil masih belum ditentusahkan. Sekiranya anda hamil semasa menggunakan *Nimodipine*, maklumkan kepada doktor anda dengan segera.

Penggunaan *Nimodipine* semasa menyusu adalah tidak disarankan kerana ia mungkin akan hadir di dalam susu ibu.

4. CARA MENGGUNAKAN *Nimodipine*

Ambil ubat anda seperti yang diarahkan oleh doktor anda.

Berapa banyak harus diambil:

2 tablet 6 kali sehari

Cara mengambil:

Telan ubat dengan segelas air.

Bila perlu diambil:

Ambil ubat anda setiap 4 jam sekali

Berapa lama perlu diambil

Ambil ubat ini selagi diarahkan oleh doktor anda. Jangkamasa rawatan biasa adalah selama 1 atau 2 minggu, bergantung kepada keadaan anda.

Jika terlupa mengambil

Jika anda terlupa dos anda, ambil sejurus anda teringat. Sekiranya hampir masa untuk dos seterusnya, anda bolehlah cuma mengambil dos seterusnya. Jangan sesekali mengambil dos berganda untuk menggantikan dos yang terlupa.

Sekiranya anda tidak pasti, tanya doktor atau ahli farmasi anda.

Jika mengambil berlebihan (terlebih dos)

Jika anda, atau sesiapa telah mengambil ubat ini secara berlebihan, anda hendaklah pergi ke Bahagian Rawatan Kecemasan Hospital terdekat atau maklumkan kepada doktor anda dengan segera. Ini perlu dilakukan walaupun tiada sebarang tanda ketidakselesaan atau keracunan. Bawa bersama bungkusan atau baki ubat biji yang selebihnya dengan anda.

Tanda-tanda terlebih dos termasuklah: kemerahan (*flush*), sakit kepala, penurunan tekanan darah mendadak, degupan jantung terlampau cepat atau terlampau perlahan dan masalah gastrousus.

5. SEMASA MENGGUNAKAN *Nimodipine*

Perkara yang perlu dilakukan

- Sekiranya anda akan mula mengambil ubat baru, ingatkan doktor anda yang anda sedang mengambil *Nimodipine*.
- Maklumkan kepada doktor, doktor gigi dan ahli farmasi bahawa anda sedang mengambil *Nimodipine*.
- Sekiranya anda akan menjalani pembedahan, maklumkan kepada pakar bedah atau pakar bus anda bahawa anda sedang mengambil *Nimodipine*. Ia mungkin mengganggu kesan ubat lain yang akan digunakan semasa pembedahan.
- Pastikan anda menjalani rawatan susulan untuk memeriksa perkembangan anda.
- Maklumkan kepada doktor anda sekiranya anda hamil semasa mengambil *Nimodipine*.
- Maklumkan kepada doktor anda sekiranya anda mengalami simptom – simptom seperti pening, pitam, sakit kepala dan muntah.

Perkara yang tidak boleh dilakukan

- Jangan berikan ubat ini kepada orang lain walaupun mereka mempunyai simptom-simptom yang sama dengan anda.
- Jangan berhenti mengambil ubat ini atau mengubah dos anda sebelum berbincang dengan doktor anda
- Jangan menggunakan *Nimodipine* untuk merawat penyakit lain kecuali atas nasihat doktor.

Perkara yang perlu diberi perhatian

- Berhati-hati semasa memandu atau mengendalikan mesin sebelum anda mengetahui kesan *Nimodipine* terhadap anda. Ubat ini mungkin menyebabkan kepeningan. Sekiranya anda mengalami simptom-simptom ini, jangan memandu, mengendalikan mesin atau melakukan aktiviti yang membahayakan.
- Sekiranya anda mengambil minuman beralkohol, ia akan memburukkan lagi kesan kepeningan.

6. KESAN-KESAN SAMPINGAN

Seperti ubat lain, *Nimodipine* boleh menyebabkan kesan sampingan, walaupun bukan semua orang akan mengalaminya. Kesan-kesan sampingan berikut mungkin berlaku:

- Sakit kepala
- Kemerahan (flush)
- Loya
- Rasa panas
- Degupan jantung perlahan
- Degupan jantung cepat
- Tekanan darah turun mendadak
- Masalah gastrousus
- Vertigo (pening dan hilang orientasi)
- Rasa lemah, kurang berdaya
- Bengkak pada kaki dan tangan
- insomnia
- rasa tidak tenteram
- rasa teruja
- agresif
- berpeluh
- pergerakan berlebihan
- kemurungan
- halangan pada usus
- platelet darah berkurang

Maklumkan kepada doktor atau ahli farmasi anda sekiranya terdapat sebarang kesan yang menyebabkan anda rasa tidak sihat. Kesan-kesan sampingan yang tidak disenaraikan mungkin akan berlaku pada sesetengah orang.

7. CARA PENYIMPANAN DAN PELUPUSAN *Nimodipine*

Cara penyimpanan

Simpan ubat dalam bungkusan asal. Simpan di tempat sejuk (bawah 30°C) dan kering. Jauhkan dari kepanasan, cahaya dan kelembapan yang berlebihan. Jangan tinggalkan ubat anda di dalam kereta.

Jauhi daripada kanak-kanak.

Pelupusan

Ubat-ubatan tidak sepatutnya dibuang seperti biasa. Tanya doktor atau ahli farmasi untuk mengetahui cara pelupusan yang sepatutnya.

8. MAKLUMAT LANJUT

Rupa, kandungan dan pembungkusan *Nimodipine*

Tablet dwicembung berbentuk bulat, tanpa garis pembelahan dan berwarna jingga kekuningan

Pembungkusan: Blister strip dibungkus dalam 30, 60 & 120 biji tablet sekotak.

Bahan-bahan:

Bahan aktif: setiap tablet mengandungi 30mg nimodipine

Bahan lain: povidone, colloidal silica anhydrous, magnesium stearate, microcrystalline cellulose, opadry white, yellow ferric oxide, crospovidone

No pendaftaran: MAL09100243A

9. PEMEGANG PENDAFTARAN DAN PENGILANG

Dikilangkan oleh

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben, Germany

Untuk

Hexal AG
Industriestraße 25,
83607 Holzkirchen,
Germany

Pemegang pendaftaran produk

IMEKS Pharma Sdn. Bhd.
No. 1 & 2, Jalan 6/33B,
MWE Commercial Park,
52000 Kuala Lumpur, Malaysia

Tarikh kemaskini Disember 2011

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about **Nimodipine**. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this entire leaflet carefully before you start to take your medicine. This medicine is for you. Never give it to other people even if their condition appears to be the same as yours. If you have any questions about this medicine ask your pharmacist. Keep this leaflet, you may need to read it again.

1. WHAT IS **Nimodipine** USED FOR

Nimodipine is used to prevent or to treat lack of blood supply in the brain caused by narrowing of the blood vessels after a haemorrhage (burst blood vessel in the brain).

2. HOW **Nimodipine** WORKS

Nimodipine belongs to a group of drugs called calcium channel blockers. It 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.

3. BEFORE YOU TAKE **Nimodipine**

Do not take this medicine if

- You are allergic to the active ingredient or related derivatives any ingredients in the formulation or any other similar medicines.
- You had recent episode of heart attack
- You had recent episode of chest pain (angina)

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

Before you start taking this medicine

Tell your doctor if you:

- have allergy to any other medicines, food, preservatives or dyes.
- have liver problems
- have kidney problems
- have very low blood pressure

- have heart problems,
- have fluid retention in the brain.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription.

These medicines may be affected by **Nimodipine**, or may affect how well it works. You may need different amount of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid.

Tell your doctor if you are taking:

- Other blood pressure lowering medicines
- Medicines of the same group like amlodipine and felodipine
- Cimetidine (for ulcers)
- Anti-epileptics medicines (e.g: phenobarbital, phenytoin, valproic acid and carbamazepine)
- Antibiotics (e.g. erythromycin, rifampicin)
- antifungal (e.g. ketoconazole, itraconazole and fluconazole)
- Anti-viral (e.g. indinavir, ritonavir, nelfinavir, saquinavir and zidovudine),
- Grape fruit juice

Pregnancy and lactation

The safety of **Nimodipine** use during pregnancy is not fully established. If you are pregnant while taking **Nimodipine**, consult your doctor immediately. Nursing is not recommended while on **Nimodipine** as it might be excreted in breast milk.

4. HOW TO TAKE **Nimodipine**

Take your medication exactly as directed by your doctor.

How much to take:

2 tablet six times a day.

How to take:

Swallow the tablet with a glass of water.

When to take:

The tablets should be taken at 4 hours

intervals.

How long to take it

Continue taking your medicine for as long as your doctor tells you. The treatment normally last for 1 or 2 weeks, depending on your condition.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally. 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 that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much

If you or anyone else takes too many tablets, tell your doctor or go to your nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of an overdose may include: reddening (flush), headaches, higher drop in blood pressure, heart beat too fast or too slow and gastrointestinal problems.

5. WHILE YOU ARE USING **Nimodipine**

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **Nimodipine**.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking **Nimodipine**.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking **Nimodipine**. It may affect other medicines used during surgery.
- Keep all of your doctor's appointments so that your progress can be checked.
- Tell your doctor if you become pregnant while taking **Nimodipine**.

- Contact your doctor if you experience symptoms such as dizziness, fainting, headache and vomiting.

Things you must not do

- 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.
- Do not take *Nimodipine* to treat any other complaint unless your doctor tells you to.

Things to be careful of

- Be careful driving or operating machinery until you know how *Nimodipine* affects you. It may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
- Concomitant intake of alcohol could worsen the effects.

6. POSSIBLE SIDE EFFECTS

Like all medicines, *Nimodipine* can cause side effects, although not everybody gets them. The following side effects may happen:

- Headache
- Reddening (flush)
- Nausea
- Sensation of warmth or heat,
- Slow heart beat
- Rapid heart beat
- higher drop in blood pressure
- gastrointestinal complaints
- vertigo (dizzy and disorientated)
- feeling weak, lack of strength
- leg/ limbs swelling
- insomnia
- restlessness
- excitation
- aggression
- sweating
- excessive movement / restless
- depression
- bowel obstructions
- reduction in blood platelets

Tell your doctor or pharmacist if you notice anything else that is making you feel

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

7. HOW TO STORE *Nimodipine*

Storage

Keep medicines in original packaging. Store in a cool (below 30°C), dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car.

Keep all medicines out of the reach of children.

Disposal

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines.

8. PRODUCT DESCRIPTION

What *Nimodipine* looks like and contents of the pack

Yellow to orange, round, biconvex film-coated tablets without score.

Packing: Blisters of 30, 60 & 120 film-coated tablets per box.

Ingredients:

Active ingredient: each tablet contains 30mg of nimodipine

Other ingredients: povidone, colloidal silica anhydrous, magnesium stearate, microcrystalline cellulose, opadry white, yellow ferric oxide, crospovidone

Registration No: MAL09100243A

9. MARKETING AUTHORIZATION HOLDER AND MANUFACTURER

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