



腦妥® 靜脈輸注液 0.02% W/W Nimotop® Infusion Solution 0.02% W/W

主成份：nimodipine

輸注液

衛署藥輸字第018843號

品名

腦妥靜脈輸注液 十毫克(五十毫升)
腦妥靜脈輸注液 五十毫克(二百五十毫升)

成份

每瓶五十毫升的輸注液含有十毫克的nimodipine溶於五十毫升的含酒精溶劑中。
每瓶二百五十毫升的輸注液含有五十毫克的nimodipine溶於二百五十毫升的含酒精溶劑中

適應症

預防、治療因動脈瘤引起之蜘蛛膜下出血後，腦血管痙攣所引起的缺血性神經缺損。

劑型

澄清的靜脈輸注液

臨床特性

- 適應症

預防、治療因動脈瘤引起之蜘蛛膜下出血後，腦血管痙攣所引起的缺血性神經缺損。

- 劑量及給藥方式《本藥限由醫師使用》

劑量

除非有特殊的處方，一般建議的使用劑量如下：

靜脈輸注：

開始治療時，給予每小時1毫克的nimodipine(等於每小時給予5毫升Nimotop輸注液)(約等於15 µg/kg體重/小時)持續2小時。若病人可以忍受上述劑量，且病人的血壓沒有顯著的降低，在兩小時後將劑量調高至每小時給予2毫克的nimodipine(等於每小時給予10毫升Nimotop輸注液)(約等於30 µg/kg體重/小時)。體重小於七十公斤或血壓不穩定的病人的起始劑量為每小時0.5毫克的nimodipine(等於每小時給予2.5毫升Nimotop輸注液)。

腦內的輸注法

在手術進行期間，應使用新鮮配製的Nimotop稀釋液(將1毫升的Nimotop輸注液以19毫升的林格氏液稀釋)，並將其加溫至與血液同溫，再注入腦內。稀釋後的溶液在配製後應立即使用。

給藥方式

Nimotop輸注液須用輸注幫浦以連續靜脈輸注經由中央導管(central catheter)注入體內。Nimotop輸注液與下列溶液以一比四的比例經由三向活塞(three-way stopcock)給予，這些溶液包括5%葡萄糖、0.9%氯化鈉、乳酸鹽林格氏液(lactated Ringer's solution)、含有鎂的乳酸鹽林格氏液、dextrans 40 solution 或 HAES® (poly(O-2-hydroxyethyl) starch 6%)。而甘露醇(mannitol)、人類白蛋白(human albumin)以及血液也適合與Nimotop輸注液同時給藥。

三向活塞(three-way stopcock)是用於同時連接Nimotop的聚乙烯管、共同輸注液管以及中央導管。Nimotop輸注液不可加在輸注袋或瓶中，也不可與其他的藥物混合。在麻醉、手術及血管攝影的過程中，皆應持續給予Nimotop。

用藥期間

預防性使用：

靜脈輸注治療應該在出血後四天內開始使用，且在血管收縮危險性最大的期間內應持續使用，即出血後的十至十四天。

如果出血處以手術治療，則預防性使用之Nimotop輸注液的輸注時間應從手術後至少持續五天。

在靜脈輸注治療結束後，一般建議使用口服nimodipine持續治療，一天服用六次60 mg的nimodipine，每四小時服用一次，持續七天。

治療性使用：

假如顱內動脈瘤破裂導致蜘蛛膜下腔出血後，因為血管收縮所造成的缺血性神經傷害已經存在，應及早開始治療，並持續治療至少五天，至多十四天。

在靜脈輸注治療結束後，一般建議使用口服nimodipine持續治療，一天服用六次60 mg的nimodipine，每四小時服用一次，持續七天。

若在治療性或預防性給予Nimotop輸注液的期間，已使用手術處理出血源，則在手術後仍應持續至少五天的Nimotop輸注液靜脈輸注治療。

禁忌

Nimotop輸注液不可用於對nimodipine 或其所含任何賦形劑過敏者。

Nimotop輸注液不可用於不穩定型心絞痛患者或急性心肌梗塞患者發作的一個月內。

警語和注意事項

雖然目前尚未顯示nimodipine治療與顱內壓升高有直接關係，當在這些情況下或腦組織內的水分上升時(統稱腦水腫)建議密切監測顱內壓的變化。

患有低血壓(收縮壓小於100 mmHg)的病人使用時必須特別注意。

雖然本品每包含體積23.7%的酒精(以250毫升每日劑量計算，高達50公克)，可能對酒精中毒者或酒精代謝功能不全者是有利的，於懷孕或哺乳婦女、小孩和高危險群(例如肝病或癲癇患者)必須小心使用。

本品中酒精的含量可能會影響其他藥品的作用(參見“與其他藥物及其他型式的交互作用”)。

與其他藥物及其他型式的交互作用：

影響nimodipine作用的藥物：

Fluoxetine

併用nimodipine和抗憂鬱藥Fluoxetine於穩定狀態時，會導致nimodipine血中濃度升高約50%，而Fluoxetine的濃度則明顯地被降低，然而它的活性代謝產物norfluoxetine並不受影響。

Nortryptiline

併用nimodipine和nortryptiline於穩定狀態時，會導致nimodipine的濃度少許降低，然而nortryptiline的血中濃度不受影響。

受nimodipine作用影響的藥物：

降血壓藥

Nimodipine與降血壓藥併服會增強血壓降低的作用，受影響的降血壓藥如下：

- 利尿劑
- β-阻斷劑
- ACE抑制劑
- A1-拮抗劑
- 其它鈣離子阻斷劑
- α-腎上腺素阻斷劑
- PDE5抑制劑
- α-methyl dopa

然而，若無法避免同時併用這類藥物，則必須小心監測病患的狀況。

同時靜脈注射β阻斷劑可能會造成血壓更顯著的降低，且同時更減弱心臟收縮力而造成無代償性的心衰竭。

若同時併用潛在具有腎毒性的藥物(如：aminoglycosides, cephalosporins, furosemide)，或病患本身的腎功能不佳，則腎功能會變得更差。對於上述的病患，應小心監測其腎功能，若發現病人的腎功能變差，則應該考慮是否停藥。

Zidovudine

在猴子實驗同時併用抗-HIV 藥物 zidovudine i.v.和 nimodipine bolus i.v. 會導致zidovudine有顯著較高的AUC，然而分佈體積和清除率會明顯的減少。

其它形式的交互作用：

由於Nimotop輸注液的組成中含有佔體積23.7%的酒精，應特別注意與酒精不相容的藥物間之交互作用。(參見“警語和注意事項”)。

懷孕和哺乳期間的使用

懷孕期

目前並沒有在懷孕婦女上有足夠適當且控制良好的研究。在懷孕期間如果必須使用nimodipine輸注液時，應該依據臨床狀況仔細評估使用nimodipine輸注液的好處以及可能造成的危險性，再決定是否使用。

哺乳期

已知nimodipine和其代謝物存在母乳中的濃度與存在母體的血中濃度相同，建議哺乳期的婦女在使用本品時建議不要哺乳給嬰兒。

生殖能力

在一體外受精個案中，其精子頭部會和鈣離子拮抗劑產生可逆性的生物化學變化，可能會導致精子的功能受損。

對駕駛及操作機械能之影響

一般而言，駕駛能力及操作機械的能力變差可能與頭暈的發生有關。假如必須使用Nimotop輸注液，這樣的影響一般說來不是很重要。

藥物不良反應

表列出不佳反應

藥物不良反應(ADR)是依據nimodipine用於治療動脈瘤性蜘蛛網膜下腔出血的臨床試驗，以CIOMS III發生頻率分類(安慰劑對照試驗：nimodipine組N=703；安慰劑組N=692，無對照組試驗：nimodipine組N=2496；至2005年8月31日為止)，如下所列：

Nimodipine藥品不良反應(ADR)通報的頻率總結於下表。同個發生頻率的組別中，不良反應依嚴重性遞減列出。發生頻率定義為：

- 非常常見 (≥ 1/10)，
- 常見 (≥ 1/100至 < 1/10)，
- 不常見 (≥ 1/1000至 < 1/100)，
- 很少見 (≥ 1/10000至 < 1/1000)，
- 非常少見 (< 1/10000)。

藥物不良反應

系統器官分類 (MedDRA)	不常見	少見
血液和淋巴系統	血小板減少	
免疫系統	過敏反應、紅疹	
神經系統	頭痛	
心臟疾病	心跳過速	心搏徐緩
血管疾病	低血壓、血管舒張	
胃腸道疾病	噁心	腸阻塞
肝膽疾病		短暫性肝臟酵素增加
一般疾病和注射部位症狀		注射和輸注部位的反應、輸注部位(血栓)靜脈炎

藥物過量

中毒的症狀

可預期的急性藥物過量症狀是血壓顯著地降低，心跳加速或心跳減緩，以及(口服給藥之後)腸胃不適與噁心。

中毒的治療

若急性藥物過量的情況發生，則應立即停止Nimotop輸注液的治療，應依據症狀給予緊急的治療措施。如果是口服給藥，緊急的治療措施應為洗胃並給予活性炭。若血壓顯著降低，則可以靜脈注射dopamine或 noradrenaline。由於並沒有已知特定的解毒劑，後續其他副作用的治療則是依據最顯著的症狀加以處理。

藥理學特性

藥效學特性

Nimodipine 具有抗腦血管收縮及抗缺血的活性。在體外試驗中，nimodipine可預防或消除各種血管活性的物質(如：血清素，前列腺素，以及組織胺)或血液及血液分解物所引起的血管收縮反應。

Nimodipine同時也具有神經藥理學及精神藥理學方面的特性。

對於發生急性腦血流病變的病人所進行的研究發現，nimodipine可使腦血管舒張並促進腦部血流的循環。一般來說，在原來受損或血流量不足的部位，增加的血流量會遠比正常的部位要多。

Nimodipine會顯著地降低蜘蛛膜下腔出血病人因缺血所造成的神經性傷害，並降低致死率。

藥動學特性

吸收

口服nimodipine活性物質幾乎可以完全被人體吸收，在最高試驗劑量下(90毫克)，血中最高濃度和曲線下面積與劑量間成比例地增加。

靜脈注射時的分佈體積(Vss，二室模式)是0.9-1.6 l/kg體重，總(全身)清除率是0.6-1.9 l/h/kg。

蛋白質結合和分佈

97-99%的nimodipine會與血漿中的蛋白質結合。

代謝、排除和排泄

Nimodipine經由cytochrome P450 3A4代謝排除。

生體可用率

由於約85-95%肝臟首渡效應，絕對生體可用率是5-15%。

臨床前安全性資料

依據單一劑量和重複劑量的毒性、基因毒性、致癌性和男性及女性生殖能力試驗的臨床前資料顯示依人體沒有特別毒性，懷孕大白鼠每天每公升給予30毫克或更高的劑量時，會抑制胎兒生長並導致胎兒體重減少，每天每公升給予100毫克時會發生胎兒致死的可能。目前尚未觀察到致畸胎毒性，在兔子的試驗，每天每公升給予高達10毫克的劑量並無胎毒性及致畸胎毒性產生。在一項大白鼠出生至出生後的研究，每天每公升給予10毫克或更高劑量可觀察到致死率和生長遲緩的現象，此發現隨後的試驗中並未被證實。

藥劑特性

賦形劑

每個50 mL的瓶內包含：Ethanol 96%，macrogol 400, sodium citrate dihydrate (0.1 g ≅ 1.0 mmol sodium), anhydrous citric acid, water for injection.

每個250 mL的瓶內包含：Ethanol 96%，macrogol 400, sodium citrate dihydrate (0.1 g ≅ 1.0 mmol sodium), anhydrous citric acid, water for injection.

配伍禁忌

由於Nimotop輸注液的有效成份會被聚氯乙烷(PVC)所吸收，所以只能使用聚乙烯(PE)的輸注管。Nimotop輸注液的有效成份對光有些許的敏感，應避免直接在日光下使用。如果在輸注過程中無法避免直接暴露在日光下，應使用黑色、棕色、黃色或紅色的玻璃注射器及連接管，或是將輸注幫浦及連接管以不透明材質包裹。然而，若Nimotop是在漫射的日光或人造光之下給藥，則不需特別的保護措施可達十小時。

操作指南

為了正確地將針頭穿刺入複蓋的注射瓶塞，建議使用尖細的注射針。禁止使用粗的輸注針頭，因為可能會導致瓶塞破裂或產生凹痕，及瓶塞可能因為施力過當而掉入注射瓶中。

注射用藥於使用前須先經肉眼觀察產品有無異狀或顏色變化，任何使用後殘餘的輸注液不可保留供下次使用。

儲存注意事項

藥瓶移出紙盒後，應避免光線直接照射。

Nimotop輸注液在過期後則不應使用。

應將藥物置於兒童無法觸及之處。

製造廠：

Bayer Pharma AG
廠址：D-51368 Leverkusen, Germany
瓶裝附輸注器之供應商：Fresenius Kabi AG
藥商：台灣拜耳股份有限公司
地址：台北市信義路五段7號54樓
電話：(02)81011000
網址：www.bayerpharma.com.tw

Nimotop Infusion Solution / CCDS5 / TW07 / 022013

Bayer



Nimotop® Infusion Solution 0.02% W/W

Active substance: nimodipine

Infusion solution

1. Name of the medical product

Nimotop solution for infusion 10 mg (50 mL)
Nimotop solution for infusion 50 mg (250 mL)

2. Qualitative and Quantitative Composition

1 bottle of Nimotop solution for infusion 10 mg (50 mL) contains 10 mg nimodipine in 50 mL alcoholic solvent.
1 bottle of Nimotop solution for infusion 50 mg (250 mL) contains 50 mg nimodipine in 250 mL alcoholic solvent.
< For a full list of excipient(s) see section "List of excipients" >

3. Pharmaceutical Form

Clear intravenous solution for infusion

4. Clinical Particulars

4.1 Indications

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

4.2 Dosage and method of administration

4.2.1 Dosage regimen

Unless otherwise prescribed, the following dosage is recommended:

Intravenous infusion:

At the beginning of treatment 1 mg nimodipine (= 5 ml Nimotop infusion solution/h) for 2 h (about 15 µg/kg body weight/h). If this is well tolerated, and particularly if there is no marked reduction in blood pressure, the dose is increased after 2 h to 2 mg nimodipine (= 10 ml Nimotop infusion solution/h) (about 30 µg/kg body weight/h).

Patients whose bodyweight is appreciably below 70 kg or who have labile blood pressure should be started with a dose of 0.5 mg nimodipine (= 2.5 ml Nimotop infusion solution/h).

Intracranial installation:

During surgery a freshly prepared dilute solution of nimodipine (1 ml of Nimotop solution for infusion and 19 ml of Ringer solution) warmed up to blood temperature may be instilled intracranially. This dilution solution of Nimotop solution for infusion must be used immediately after preparation.

4.2.2 Method of administration

Nimotop infusion solution is administered as a continuous i.v. infusion via a central catheter using an infusion pump. It should be given via a three-way stopcock together with either glucose 5 %, sodium chloride 0.9 %, lactated Ringer's solution, lactated Ringer's solution with magnesium, dextran 40 solution or HAES® (poly(O-2-hydroxyethyl) starch 6 % in a ratio of about 1:4 (NIMOTOP:co-infusion). Also mannitol, human albumin or blood are suitable for co-infusion.

The three-way stopcock should be used to connect the Nimotop polyethylene tube with the co-infusion line and the central catheter.

Nimotop solution must not be added to an infusion bag or bottle and must not be mixed with other drugs.

Administration of Nimotop should be continued during anaesthesia, surgery and angiography.

4.2.3 Duration of use

Prophylactic use:

Intravenous therapy should be started no later than 4 days after the haemorrhage and be continued during the period of maximum risk of vasospasm, i.e. up to 10-14 days after the haemorrhage.

If during prophylactic administration of Nimotop solution for infusion, the source of the haemorrhage is treated surgically, intravenous treatment with Nimotop solution for infusion should be continued post-operatively for at least 5 days.

After the end of the infusion therapy, it is advisable to continue with oral administration of 6 x 60 mg nimodipine daily at 4 h intervals for about a further 7 days.

Therapeutic use:

If ischemic neurological disturbances caused by vasospasm after aneurysmal subarachnoid haemorrhage are already present, treatment should be started as early as possible and be continued for at least 5 days up to a maximum of 14 days. Thereafter oral administration of 6 x 60 mg nimodipine per day at 4 h intervals for 7 days is recommended.

If during therapeutic administration or prophylactic administration of Nimotop solution for infusion, the source of the hemorrhage is treated surgically, intravenous treatment with Nimotop solution for infusion should be continued post-operatively for at least 5 days.

4.3 Contraindications

Nimodipine solution for infusion must not be used in cases of hypersensitivity to nimodipine or to any of the excipients.

Nimodipine solution for infusion should not be administered to patients during or within one month of a myocardial infarction or an episode of unstable angina.

4.4 Special warnings and special precautions for use

Although treatment with nimodipine 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 edema).

Caution is required in patients with hypotension (systolic blood pressure lower than 100 mm Hg).

This medicinal product contains 23.7 vol% ethanol (alcohol), i.e. up to 50 g per daily dose (250 ml). This may be harmful for those suffering from alcoholism or impaired alcohol metabolism and should be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

The amount of alcohol in this medicinal product may alter the effects of other medicines. (see "Interaction with other medicinal products and other forms of interaction").

4.5 Interactions with other medicinal products and other forms of interaction

4.5.1 Drug that affect nimodipine:

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.

Nortriptyline

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

4.5.2 Effects of nimodipine on other drug:

Blood pressure lowering drugs

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

- diuretics,
- β-blockers,
- ACE inhibitors,
- A1-antagonists,
- other calcium antagonists,
- α-adrenergic blocking agents,
- PDE5 inhibitors,
- α-methyl dopa.

However, if a combination of this type proves unavoidable particularly careful monitoring of the patient is necessary. Simultaneous intravenous administration of β-blockers may lead to mutual potentiation of negative inotropic action going as far as decompensated heart failure.

Renal function can deteriorate if potentially nephrotoxic drugs (e.g. aminoglycosides, cephalosporins, furosemide) are given simultaneously, and also in patients whose renal function is already impaired. Renal function must be monitored carefully in such cases, and if a deterioration is found discontinuation of the treatment should be considered.

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.

4.5.3 Other forms of interaction:

Since Nimotop solution for infusion contains 23.7 % vol-% of alcohol, interactions with alcohol-incompatible drugs should be taken into consideration. (see "Special warnings and precautions for use").

4.6 Pregnancy and 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 weighted 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.

Fertility

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.

4.7 Effect 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. In case of using Nimotop infusion solution, this influence will generally not be of importance.

4.8 Undesirable effects

Tabulated list of adverse reactions

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 (≥ 1/10),
- common (≥ 1/100 to < 1/10),
- uncommon (≥ 1/1,000 to < 1/100),
- rare (≥ 1/10,000 to < 1/1,000),
- very rare (< 1/10,000).

Table 01: ADR

System Organ Class (MedDRA)	Uncommon	Rare
Blood and the lymphatic system disorders	Thrombocytopenia	
Immune system disorders	Allergic reaction Rash	
Nervous system disorders	Headache	
Cardiac disorders	Tachycardia	Bradycardia
Vascular disorders	Hypotension Vasodilatation	
Gastrointestinal disorders	Nausea	Ileus
Hepato-biliary disorders		Transient increase in liver enzymes
General disorders and administration site conditions		Injection and infusion site reactions Infusion site (thrombo) phlebitis

4.9 Overdose

Symptoms of intoxication

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

Treatment of intoxication

In the event of acute overdosage treatment with Nimotop solution for infusion 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 noradrenaline can be administered intravenously. Since no specific antidote is known, subsequent treatment for other side effects should be governed by the most prominent symptoms.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Nimodipine has a predilective cerebral anti-vasoconstrictive and anti-ischemic 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 ischemic neurological damage in patients with subarachnoid hemorrhage and the mortality rate are significantly reduced by nimodipine.

5.2 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 %.

5.3 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 embryolethality 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.

6. Pharmaceutical particulars

6.1 List of excipients

Each 50 mL bottle contains:

Ethanol 96%, macrogol 400, sodium citrate dihydrate (0.1 g ± 0.1 mmol sodium), anhydrous citric acid, water for injection.

Each 250 mL bottle contains:

Ethanol 96%, macrogol 400, sodium citrate dihydrate (0.5 g ± 5.1 mmol sodium), anhydrous citric acid, water for injection.

6.2 Incompatibilities

Since the active substance of Nimotop solution for infusion is absorbed by polyvinyl-chloride (PVC), only polyethylene (PE) infusion tubing may be used.

The active substance of Nimotop infusion solution is slightly light-sensitive such that its use in direct sunlight should be avoided. If direct exposure to sunlight is unavoidable during an infusion, black, brown, yellow or red glass syringes and connecting tubing should be used, or the infusion pump and the tubing be protected by opaque wrappings. However, no special protective measures are needed for up to 10 h if Nimotop is being given in diffuse daylight or in artificial light.

7. Instructions for use/handling

Parenteral drug products should be inspected visually for particulate matter and color change prior to administration. Any residual solution should not be kept for later use.

8. Special precautions for storage

Protect from direct sunlight, if the bottle is removed from the carton.

Nimotop infusion solution must not be used after the expiry date.

Keep drugs out of reach of children.

Bayer Pharma AG, D-51368 Leverkusen, Germany
IV set: Clinica Infusionstechnik, GmbH & Co.
Nimotop Infusion Solution / CCDS5 / TW07 / 022013

Bayer