Takipril®

prilocaine hydrochloride
20 mg/ml hyperbaric

Composition
TAKIPRIL contains 20 mg/mL of prilocaine hydrochloride as an active substance. Other ingredients are glucose, sodium hydroxide 1N and water for injection.

Description
TAKIPRIL is a clear and colourless solution for injection that contains prilocaine hyperbaric, a local anaesthetic, belonging to the category of the amides. **TAKIPRIL** is used to anaesthetise specific parts of the body and prevent pain during surgery in adults. By means of the excipient glucose, the density of **TAKIPRIL** is 1.026 g/g at 20°C, equivalent to 1.021 g/g at 37°C. This medicinal product contains less than 1 mmol sodium (23 mg) per dose (maximum dose equal to 4 mL of TAKIPRIL), i.e. essentially “sodium-free”.

Pharmacology
Pharmacodynamic
Prilocaine is an amide-type local anaesthetic. Prilocaine inhibits the function of the excitable structures (e.g. all types of nerve fibres [sensory, motor, autonomous nerve fibres]). It inhibits the excitability of sensory pain receptors and the conductivity of the sensory nerve fibres, at local level and in a reversible way, reducing the perception of pain and, subsequently, that of cold, heat, touch and pressure.

Prilocaine reduces membrane permeability to sodium. This reduces the excitability of the nerve fibres in accordance with its concentration, through reducing the sudden peak sodium permeability, needed to form the potential for action. The effect depends on the pH of the substance and the pH of the environment. The local anaesthetic effect is due to the protonated form. In inflamed tissues, the effect of the local anaesthetics is lower because of the lower pH of the environment.

Pharmacokinetic
The plasma concentration should be negligible for intrathecal use. The terminal elimination half-life of prilocaine is 1.6 hours. The plasma protein bond is approximately 55%. The bioavailability of prilocaine at the application site is 100%.

Indications
TAKIPRIL is indicated in adults for spinal anaesthesia in short term surgical procedures (not more than 45 minutes).

Contraindications
TAKIPRIL is must not be used in patients with:
- Hypersensitivity to prilocaine hydrochloride, other amide-type local anaesthetics or to any of the excipients
- Serious problems with cardiac conduction
- Severe anaemia
- Decompensated cardiac insufficiency
- Cardiogenic and hypovolemic shock
- Congenital or acquired methemoglobinemia

It is also necessary to take into consideration general and specific contraindications for the technique of subarachnoid anaesthesia.

Dose and Administration
Restricted to hospital use only Spinal anaesthesia must only be administrated by (or under the supervision of) specialist medical personnel with the necessary knowledge and experience. The equipment, drugs and personnel capable of dealing with an emergency, e.g. maintaining the patency of the airways and administering oxygen, must be immediately available, since in rare cases severe reactions, sometimes with a fatal outcome, have been reported after using local anaesthetics, even in the absence of individual hypersensitivity in the patient’s case history. If signs of acute systemic toxicity or total spinal block are observed, the injection of the local anaesthetic must be stopped immediately.

Posology
Posology must be established on an individual basis in accordance with the characteristics of the specific case. When determining the dose, take into consideration the patient’s physical condition and the concomitant administration of other medicinal products.The lowest possible dose should be chosen.

The duration of action is dose-dependent. The indications relating to recommended doses are valid in adults of average height and weight (approximately 70 kg) for obtaining an effective block with one single administration. There are wide individual variations with regard to extent and duration of action. The experience of the anaesthetist and knowledge of the patient’s general condition are essential for establishing the dose.

Adult population:

	mL	mg	Average duration of action (minutes)
Extension of sensory blockade required T10	2-3	40-60	Approx. 100-130

Paediatric population:
TAKIPRIL must not be used in children and adolescents.
The safety and efficacy of Prilocaine in paediatric population have not been established. No data are available. The use of Prilocaine in children younger than 6 months is contraindicated.

Special population:
It is advisable to reduce the dose in patients in a compromised general condition.
In addition, in patients with established concomitant disorders (e.g. vascular occlusion, arteriosclerosis, diabetic polyneuropathy) a reduced dose is indicated.
In the case of compromised liver or kidney function a lower dosage range is recommended.

Method of administration:
TAKIPRIL is injected via the spinal route.
Inject **TAKIPRIL** via intrathecal route into the intervertebral space L2/L3, L3/L4 and L4/L5. Slowly inject the entire dose and check the patient’s vital functions extremely carefully maintaining continuous verbal contact.

If the patient is in a seated position, the injected solution diffuses mainly in a caudal direction (in the direction of the sacrum); if the patient is lying down, the anaesthetic diffuses by gravity according to the patient’s position (Trendelenburg and anti-Trendelenburg). In general the following points should be taken into consideration:
1. Choose the lowest possible dose!
2. Administer the injection slowly, after having aspirated a minimum quantity of CSF to confirm the correct position
3. Do not inject into infected areas!

4. Subarachnoid anaesthesia is contraindicated in patients taking anticoagulants

Warnings and Precautions
Due to the glucose content **TAKIPRIL** is only to be used for spinal anaesthesia. It is not recommended for the use in epidural anaesthesia.

Spinal anaesthesia must only be administered by (or under the supervision of) specialist medical personnel with the necessary knowledge and experience. The doctor in charge is responsible for taking the measures needed to avoid an intravascular injection.

In addition, it is essential for the doctor to know how to recognize and treat undesirable effects, systemic toxicity and other complications. If signs of acute systemic toxicity or total spinal block are observed, the injection of the local anaesthetic must be stopped immediately.

Some patients require special attention in order to reduce the risk of serious undesirable effects, even when locoregional anaesthesia constitutes the optimum choice for the surgical intervention:

- Patients with total or partial heart block, since local anaesthetics can suppress myocardial conduction.
- Patients with high grade cardiac decompensation. The risk of methemoglobinemia must also be taken into consideration.
- Patients with advanced liver or kidney damage.
- Elderly patients and patients in reduced general condition.
- Patients treated with class III antiarrhythmic agents (e.g. amiodarone). These patients should be subjected to careful observation and ECG monitoring, since cardiac effects may be added.
- In patients with acute porphyria, **TAKIPRIL** should only be administered when there is a compelling indication for its use, as **TAKIPRIL** may potentially precipitate porphyria. Appropriate precautions should be taken in all patients with porphyria.

Ensuring the presence of reliable venous access is recommended.

As with all local anaesthetics, a drop in arterial pressure may occur and cardiac frequency may slow.

In high risk patients, the recommendation is to improve their general condition prior to the intervention.

A rare, but serious, undesirable effect of spinal anaesthesia is high or total spinal block, with consequent cardiovascular and respiratory depression. Cardiovascular depression is induced by an extended block of the sympathetic nervous system, which may induce severe hypotension and bradycardia to the point of cardiac arrest. Respiratory depression is induced by the block of the respiratory musculature and the diaphragm.

Especially in elderly patients and patients in the final period of pregnancy there is an increased risk of high or total spinal block, consequently it is advisable to reduce the anaesthetic dose.

Particularly in the case of elderly patients, an unexpected drop in arterial pressure may occur as a complication of spinal anaesthesia.

Rarely, neurological damage may occur after spinal anaesthesia, manifesting as paresthesia, loss of sensitivity, motor weakness and paralysis. Occasionally these symptoms persist.

There is no evidence that neurological disorder, such as multiple sclerosis, hemiplegia, paraplegia or neuromuscular disorders may be negatively influenced by spinal anaesthesia. Nevertheless, it should be used with care. Careful evaluation of the risk-benefit ratio is recommended prior to treatment.

Effect on ability to drive and use machines
In the case of using Prilocaine hydrochloride hyperbar, the doctor is responsible for deciding in each individual case if the patient can drive or use machines.

Pregnancy and Lactation
There are no adequate data from the use of prilocaine in pregnant women. Prilocaine is able to cross the placenta. Cases of neonatal methaemoglobinaemia requiring treatment have been reported following paracervical block or pudendal anaesthesia with prilocaine during obstetric use. Cases of foetal bradycardia with fatalities have occurred with other amide-type local anaesthetics following paracervical block. Studies in animals have shown reproductive toxicity. **TAKIPRIL** may therefore only be administered in cases where there is a compelling indication for its use. Use of prilocaine for paracervical block or pudendal anaesthesia should be avoided.

It is not known whether prilocaine passes into breast milk. If administration is required during lactation, breast-feeding can be resumed approximately 24 hours after treatment.

Fertility
No human data on the effect prilocaine of fertility are available.

Drug Interactions
Prilocaine may potentiate the formation of methemoglobin by medicinal products known to induce methemoglobin (e.g. sulfonamides, antimalarials, sodium nitroprussiate and nitroglycerin).

In the event of the concomitant use of prilocaine and other local anaesthetics or medicinal products with a chemical structure similar to prilocaine, e.g. certain antiarrhythmics such as aprindine, lidocaine, mexiletine and tocainide, it is possible for undesirable effects to be added. No studies have been performed on interactions between prilocaine and class III antiarrhythmics (e.g. amiodarone), but care must also be taken in this case.

The combination of various local anaesthetics induces additional effects which affect the cardiovascular system and the CNS.

Adverse Reactions
TAKIPRIL is unlikely to cause serious side effects unless it is accidentally injected in the wrong way or used together with other local anaesthetics.

The frequency of onset of undesirable effects is classified as follows: 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).

The possible undesirable effects due to the use of **TAKIPRIL** are generally similar to the undesirable effects of other local anaesthetics for spinal anaesthesia from the amide group. The undesirable effects induced by the medicinal product are difficult to distinguish from the physiological effects of the nerve block (e.g. reduction in arterial pressure, bradycardia, temporary urine retention), from direct effects (e.g. spinal hematoma) or the indirect effects of the injection (e.g. meningitis), or from the effects due to the loss of cerebrospinal liquid (e.g. post-spinal headache).

Very common:
- Vascular disorders: hypotension
- Gastrointestinal disorders: nausea

Common
- Disorders of the nervous system: paresthesia, dizziness
- Gastrointestinal disorders: vomiting

Uncommon:
- Disorders of the nervous system: signs and symptoms of CNS toxicity (convulsions, circumoral paresthesia, feeling of numbness affecting the tongue, hearing problems, visual problems, shaking, tinnitus, speech problems, loss of consciousness)
- Vascular disorders: bradycardia, hypertension
- Musculoskeletal and connective tissue: Back pain, temporary muscle weakness

Rare:
- Blood and lymphatic system disorders: methemoglobinemia, cyanosis
- Immune system disorders: allergic reactions, anaphylactic reactions/ anaphylactic shock, itching
- Disorders of the nervous system: neuropathy, lesions of peripheral nerves, arachnoiditis
- Eye disorders: diplopia
- Cardiac disorders: cardiac arrest, arrhythmia
- Respiratory disorders: respiratory depression

The signs of intoxication from local anaesthetics are similar for any injected preparation, both in the way in which they manifest, and in their treatment.

In spite of the demonstrated high clinical tolerability of **TAKIPRIL**, undesirable toxic effects cannot be excluded in the presence of plasma levels above a critical threshold. These undesirable effects mainly manifest as symptoms affecting the central nervous and cardiovascular system.

The most effective prophylactic measures are scrupulous compliance with the recommended posology for **TAKIPRIL**, with it being essential for the doctor to check its action (visual and verbal contact with the patient), as well as careful aspiration prior to injecting the solution.

Mild undesirable effects (feeling dizzy or dazed) can be attributed to moderate overdose and generally resolve rapidly after reducing the dose or halting administration of **TAKIPRIL**.

Serious undesirable effects are attributable to significant overdose and/ or accidental injection of local aesthetic into a blood vessel. They manifest as symptoms affecting the central nervous system (restlessness, speech problems, disorientation, dizziness, muscle contractions, cramps, vomiting, loss of consciousness, respiratory arrest and mydriasis) and the cardiocirculatory system (raised arterial pressure and pulse frequency, arrhythmia, drop in arterial pressure, asystole) following irritation and/or depression of the cerebral cortex and the cerebral marrow.

In addition, following inhibition or block of the cardiac conduction system, cardiac frequency may slow down and myocardial depression may occur.

Any problems relating to metabolism (liver) or excretion (kidney) of **TAKIPRIL** should also be considered as other possible causes of undesirable effects.

Adverse reaction reporting

If you have any side effects or discomfort during or after using this medicine, consult your doctor, pharmacist, or nurse. You can also report any side effects or discomfort directly to the pharmaceutical company via +62 821-3337-8997 or at https://www.bbraun.co.id/en/about-us/contact.html.

By reporting side effects, you can help provide more information about the safety of this medicine.

Overdose and Treatment

It is unlikely that **TAKIPRIL**, at the recommended posology, will induce plasma levels capable of inducing systemic toxicity.

Acute systemic toxicity

Systemic undesirable effects, which may occur in the presence of plasma levels of more than 5–10 micrograms of prilocaine/mL, are iatrogenic, pharmacodynamic or pharmacokinetic origin and concern the central nervous system and the cardiocirculatory system. Iatrogenic undesirable effects occur due to:
- Injection of an excessive quantity of solution
- Accidental injection into a vessel
- Incorrect patient position
- High spinal anaesthesia (marked drop in arterial pressure)

In the case of accidental intravenous administration, the toxic effect occurs within 1–3 minutes. On the contrary, in the case of overdose maximum plasma concentrations are only reached after 20–30 minutes, depending on the injection site, and the onset of signs of toxicity is delayed.

Signs of overdose can be classified into two different sets of symptoms which differ in terms of quality and intensity:

a) Symptoms affecting the central nervous system

Generally, the first symptoms are paresthesia in the mouth area, feeling of numbness of the tongue, feeling dazed, problems with hearing and tinnitus. Visual problems and muscle contractions are more severe and precede a generalized convulsion. These signs must not be erroneously mistaken for neurotic behaviour.

Subsequently loss of consciousness and tonic-clonic seizure may occur, generally lasting between a few seconds and a few minutes.

The convulsions are immediately followed by hypoxia and increased levels of carbon dioxide in the blood (hypercapnia), attributable to increased muscular activity associated with respiratory problems. In serious cases respiratory arrest may occur. Acidosis potentiates the toxic effects of local anaesthetics.

The reduction or improvement of symptoms affecting the central nervous system can be attributed to the redistribution of local anaesthetics outside the CNS, with its consequent metabolism and excretion. Regression may be rapid, unless enormous quantities have been used.

b) Cardiovascular symptoms

In serious cases cardiovascular toxicity may occur. Hypotension, bradycardia, arrhythmia and also cardiac arrest may occur in the presence of a high systemic concentration of local anaesthetics.

The first signs of toxic symptoms affecting the central nervous system generally precede toxic cardiovascular effects. This statement does not apply if the patient is under general anaesthesia or heavily sedated with medicinal products such as benzodiazepine or barbiturates.

Treatment of acute systemic toxicity

The following measures must be taken immediately:
- Stop administration of **TAKIPRIL**.
- Ensure an adequate supply of oxygen: keep the airways clear, administer O2, and artificial ventilation (intubation) if required.

In the event of cardiovascular depression circulation must be stabilized. If convulsions occur and do not resolve spontaneously after 15–20 seconds, the administration of an intravenous anticonvulsant is recommended.

Analeptics with a central action are contraindicated in the case of intoxication caused by local anaesthetics.

In the event of serious complications, when treating the patient it is advisable to obtain the assistance of a doctor specializing in emergency medicine and resuscitation (e.g. anaesthetist).

Methemoglobinemia
Methemoglobinemia may follow the administration of prilocaine. **TAKIPRIL** is contraindicated for techniques of regional anaesthesia requiring continuous administration. The doses used in subarachnoid anaesthesia do not induce blood levels capable of inducing methemoglobinemia, which occurs if the quantity of prilocaine hydrochloride administered is equal to or higher than 600 mg.

There is a metabolite of prilocaine, o-toluidine, which can induce methemoglobin formation. In general, methemoglobin formation is clinically negligible, except in cases of extremely severe anaemia and high grade cardiac decompensation.

Patients with severe anaemia may develop hypoxia. It is important to exclude other serious causes of cyanosis, e.g. acute hypoxia and/or cardiac insufficiency.

Treatment of methemoglobinemia:
Proven methemoglobinemia resolves 15 minutes after the i.v. injection of 2–4 mg/kg body weight of toluidine blue.

Additional information:
Even low concentrations of methemoglobin can alter measurements of pulsoxymetria.

Storage
Do not store **TAKIPRIL** above 30°C. Do not refrigerate. Store in original package in order to protect from light.
Keep out of the reach and sight of children.
Do not use **TAKIPRIL** after the expiry date which is stated on the ampoules and the outer carton. The expiry date refers to the last day of that month.

Use immediately after first opening.
Do not use **TAKIPRIL** if the solution is not clear and free from particles.
Any remaining product must be disposed of.

Presentation
Box of 10 ampoules each containing 5 mL of solution for injection.

Reg. No: DKI2151200243A1

ON MEDICAL PRESCRIPTION ONLY

Manufactured by:
Sintetica SA
Switzerland

Registered by:
PT B. Braun Pharmaceutical Indonesia
Karawang - Indonesia

***PACKAGE LEAFLET*: INFORMASI UNTUK PASIEN**

Takipril 2 % cairan injeksi

Prilocaine hydrochloride

Bacalah seluruh leaflet ini dengan hati-hati sebelum Anda mulai menggunakan obat ini untuk mendapatkan informasi yang penting untuk Anda.

- Simpanlah *leaflet* ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan di luar *leaflet* ini, tanyakan kepada dokter atau apoteker.
- Obat ini hanya diresepkan untuk Anda. Jangan memberikan obat ini untuk orang lain karena dapat memberikan efek yang buruk walaupun orang tersebut memiliki penyakit dengan gejala yang sama dengan Anda.
- Jika Anda mengalami efek samping, konsultasikan kepada dokter atau apoteker. Efek samping yang dimaksud ialah termasuk efek samping lain yang tidak tertulis dalam informasi untuk pasien ini.

Informasi yang terkandung dalam *leaflet* ini:

1. Apa itu Takipril dan pada kondisi apa digunakan?

Takipril memiliki kandungan *prilocaine hydrochloride* yang tergolong dalam kategori anestesi lokal. Takipril digunakan pada dewasa untuk menciptakan suatu kondisi anestesi pada bagian tubuh tertentu untuk menghilangkan rasa sakit yang terjadi selama prosedur operasi singkat (tidak lebih dari 45 menit)

2. Apa yang perlu Anda ketahui sebelum mendapatkan Takipril?

Takipril tidak untuk digunakan pada kondisi:

- Apabila memiliki alergi terhadap *prilocaine hydrochloride* atau salah satu bahan lain dari obat ini (tercantum dalam bagian 6).
- Apabila memiliki alergi terhadap anestesi lokal lain dari kelas yang sama (seperti *lidocaine* atau *bupivacaine*).
- Apabila mengindap anemia (kadar sel darah merah atau hemoglobin di bawah nilai normal).
- Memiliki kelainan pada pigmen/zat warna pada sel darah merah yang bernama *'methaemoglobinaemia'*.
- Memiliki masalah kesehatan atau kelainan terkait jantung.

Takipril tidak boleh diberikan pada kondisi yang telah disebutkan di atas. Jika tidak yakin, diskusikan dengan dokter yang menangani Anda.

Peringatan dan perhatian

Kondisi berikut harus disampaikan kepada dokter sebelum menggunakan Takipril jika:

- Anda memiliki tekanan darah tinggi atau masalah jantung
- Anda memiliki gangguan fungsi hati atau ginjal
- Anda mengalami kesulitan bernapas
- Anda menderita epilepsi
- Anda memiliki infeksi atau peradangan di tempat suntikan harus diberikan.
- Anda pernah diberitahu bahwa Anda memiliki penyakit langka pigmen darah yang disebut *''porphyria'* atau siapa pun di keluarga Anda memilikinya.

Jika Anda tidak yakin jika hal-hal di atas terjadi pada Anda, bicarakan dengan dokter Anda sebelum menggunakan Takipril.

Obat-obatan lain lainnya dan Takipril

Informasikan dokter atau perawat Anda jika Anda sedang mendapatkan terapi obat lain, termasuk obat-obat yang dibeli tanpa resep dokter dan obat-obatan herbal. Obat-obat berikut dapat dipengaruhi atau memengaruhi kerja Takipril:

- Anastesi lokal lainnya
- Antibiotika golongan *sulphonamides*, seperti *cotrimoxazole* (digunakan untuk mengobati infeksi yang disebabkan oleh bakteri)

- Anti-malaria (digunakan untuk mencegah atau mengobati malaria)
- Golongan nitrat (digunakan untuk mengobati masalah jantung)
- Obat-obatan untuk terapi ganguan irama jantung (aritmia), seperti *amiodrone*.

Kehamilan, menyusui dan kesuburan
Jika Anda sedang hamil atau menyusui, berpikir mungkin sedang hamil atau berencana untuk hamil, tanyakan kepada dokter Anda untuk meminta saran sebelum mendapatkan Takipril.

Mengemudi dan mengoperasikan mesin
Takipril mungkin membuat rasa mengantuk dan memengaruhi kecepatan reaksi Anda. Setelah Anda diberikan
Takipril, Anda tidak boleh mengemudi atau menjalankan alat atau mesin sampai hari berikutnya.

Takipril mengandung natrium
Takipril mengandung 2,36 mg natrium per milliliter (mL), setara dengan 118 mg per 50 mL ampul. Dokter akan mempertimbangkan hal ini jika Anda sedang menjalani diet pembatasan natrium.

3. Bagaimana cara penggunaan Takipril?
Takipril diberikan dalam bentuk obat injeksi/suntikan. Dosis yang diberikan dokter akan bergantung pada ukuran tubuh, usia dan kondisi fisik pasien. Dosis terendah akan diberikan untuk menghasilkan efek yang dibutuhkan. Takipril akan disuntikkan pada bagian tulang punggung (spinal). Obat akan mulai bekerja beberapa menit setelah disuntikkan dan efeknya perlahan-lahan akan hilang ketika efek terapinya habis.

Penggunaan pada anak-anak dan remaja
Takipril tidak boleh digunakan untuk anak dan remaja serta dikontraindikasikan pada anak dibawah 6 bulan.

Jika Takipril diberikan melebihi dosis yang seharusnya.
Efek samping yang serius karena pemberian Takipril dengan dosis yang melebihi seharusnya memiliki tanda-tanda sebagai berikut:
- Merasa pusing atau sakit kepala ringan
- Mati rasa pada bibir dan di sekitar mulut
- Mati rasa di lidah
- Masalah pendengaran
- Masalah dengan penglihatan

Untuk mengurangi risiko efek samping yang serius, dokter akan menghentikan pemberian Takipril segera setelah tanda-tanda ini muncul.
Efek samping yang lebih serius antara lain adalah gangguan bicara, otot berkedut, tremor, gemetar, kejang, kehilangan kesadaran, tekanan darah menjadi rendah, detak jantung tidak teratur, melambat atau berhenti.

4. Apakah kemungkinan efek samping Takipril?
Seperti semua obat-obatan, Takipril dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Efek samping lain yang mungkin terjadi:
Sangat sering
- Gangguan pembuluh darah: penurunan tekanan darah di bawah nilai normal (hipotensi)
- Gangguan saluran cerna: mual.

Sering
- Gangguan sistem saraf: kesemutan, pusing
- Gangguan sistem cerna: muntah

Tidak sering
- Gangguan sistem saraf: tanda dan gejala toksisitas susunan saraf pusat (kejang, kesemutan di sekeliling mulut, perasaan mati rasa yang mengenai lidah, masalah pendengaran, masalah visual, gemetar, telinga berdenging, masalah bicara, kehilangan kesadaran).
- Gangguan pembuluh darah: denyut jantung melambat, hipertensi
- Otot, tulang dan jaringan ikat: nyeri punggung, kelemahan otot sementara.

Jarang

- Gangguan darah dan sistem limfatik: berkurangnya kemampuan sel darah merah mengikat oksigen (methemoglobinemia), warna kebiru-biruan pada kulit dan selaput lendir karena kekurangan oksigen dalam darah (sianosis).
- Gangguan sistem imun: reaksi alergi, reaksi anafilaksis/syok anafilaktik, gatal
- Gangguan sistem saraf: kerusakan saraf, cedera saraf tepi, peradangan tulang belakang.
- Gangguan mata: penglihatan ganda
- Gangguan jantung: henti jantung, gangguan irama
- Gangguan pernapasan: depresi pernapasan

Tidak perlu merasa khawatir dengan daftar efek samping yang disebutkan di atas karena efek samping tidak selalu terjadi pada setiap orang.

Melaporkan efek samping
Apabila ada keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan keluhan efek samping atau konsisi tidak nyaman tersebut secara langsung ke Industri Farmasi melalui kontak +62 821-3337-8997 di https://www.bbraun.co.id/en/about-us/contact.html. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini

5. Bagaimana cara menyimpan Takipril?

- Jauhkan obat ini dari pandangan dan jangkauan anak. Jangan menggunakan obat ini setelah melebihi tanggal kedaluwarsa yang tercantum pada kemasan. Tanggal kedaluwarsa mengacu pada hari terakhir bulan yang tercantum.
- Jangan simpan pada suhu di atas 30°C.
- Jangan dibekukan
- Dokter Anda atau rumah sakit biasanya akan menyimpan Takipril dan mereka bertanggung jawab atas kualitas produk ketika telah dibuka jika tidak segera digunakan. Mereka juga bertanggung jawab untuk membuang Takipril yang tidak terpakai dengan benar.

6. Apakah yang terkandung dalam Takipril dan informasi lainnya?

Apa yang terkandung dalam Takipril?
Setiap mililiter (mL) larutan mengandung 20 mg *prilocaine hydrochloride*. Bahan lain adalah dextrose anhidrat, sodium hidroksida dan air untuk injeksi.
Bagaimana penampakan dan kemasan Takipril?
Takipril dalah cairan untuk injeksi dalam ampul 5 mL

Kemasan
Dus, berisi 10 ampul yang masing-masing mengandung 5 mL larutan untuk injeksi

No. Reg:

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:
Sintetica SA
Switzerland

Diimport dan Dipasarkan oleh :
PT. B. Braun Pharmaceutical Indonesia
Karawang – Indonesia

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