

Catapres®

Clonidine hydrochloride

Composition

1 tablet contains
(= clonidine hydrochloride)

0.075 mg or 0.150 mg 2,6-dichloro-N-2-imidazolidinylidenebenzenamine hydrochloride

Excipients

Lactose monohydrate, calcium hydrogen phosphate anhydrous, maize starch dried, silica colloidal anhydrous, povidone, starch soluble, stearic acid

Product description

Scored, white, compressed tablets, impressed with the identifying code 1C/1C for 0.075 mg and 15C/15C for 0.150 mg on one side.

Indications

Catapres® is indicated in the treatment of hypertension. Catapres® may be employed alone or concomitantly with other antihypertensive agents.

For the treatment of hypertensive crises, slow parenteral administration is especially suitable due to the rapid onset of action.

Dosage and Administration

Treatment of hypertension requires regular medical supervision. The dose of Catapres® must be adjusted according to the patient's individual blood pressure response.

As an initial daily dose in mild to moderate forms of hypertension, 0.075 mg to 0.150 mg daily are sufficient in most cases.

After a period of 2–4 weeks the dose may be increased if necessary until the desired response is achieved.

Usually doses above 0.6 mg per day do not result in a further marked drop in blood pressure.

In severe hypertension it might be necessary to increase the single dose further to 0.3 mg; this could be repeated up to three times daily (0.9 mg).

Renal insufficiency

Dosage must be adjusted

- according to the individual antihypertensive response which can show high variability in patients with renal insufficiency
- according to the degree of renal impairment

Careful monitoring is required. Since only a minimal amount of clonidine is removed during routine haemodialysis, there is no need to give supplemental clonidine following dialysis.

Pediatric Population:

There is insufficient evidence for the application of clonidine in children and adolescents younger than 18 years. Therefore, the use of clonidine is not recommended in pediatric subjects under 18 years.

Contraindications

Catapres® should not be used in patients with known hypersensitivity to the active ingredient or other components of the product, and in patients with severe bradyarrhythmia resulting from either sick sinus syndrome or AV block of 2nd or 3rd degree.

In case of rare hereditary conditions that may be incompatible with an excipient of the product (see section Special warnings and precautions) the use of the product is contraindicated.

Special Warnings and Precautions

Catapres® should be used with caution in patients with mild to moderate bradyarrhythmia such as low sinus rhythm, with disorders of cerebral or peripheral perfusion, depression, polyneuropathy, and constipation.

In hypertension caused by pheochromocytoma no therapeutic effect of Catapres® can be expected.

Clonidine, the active ingredient of Catapres®, and its metabolites are extensively excreted with the urine. Renal insufficiency requires particularly careful adjustment of dosage.

As with other antihypertensive drugs, treatment with Catapres® should be monitored particularly carefully in patients with heart failure or severe coronary heart disease.

Patients should be instructed not to discontinue therapy without consulting their physician. Following sudden discontinuation of Catapres® after prolonged treatment with high doses, restlessness, palpitations, rapid rise in blood pressure, nervousness, tremor, headache or nausea have been reported. When discontinuing therapy with Catapres®, the physician should reduce the dose gradually over 2–4 days.

An excessive rise in blood pressure following discontinuation of Catapres® therapy can be reversed by intravenous phentolamine or tolazoline (see section Interactions).

If long-term treatment with a beta-receptor blocker has to be interrupted, then the beta-receptor blocker should first be phased out gradually and then clonidine.

In patients who have developed localized skin reaction to transdermal clonidine, administration of oral clonidine therapy may be associated with the development of a generalized rash.

Patients who wear contact lenses should be warned that treatment with Catapres® may cause decreased lacrimation.

In particular, when clonidine is used off-label concomitantly with methylphenidate in children with ADHS, serious adverse reactions, including death, have been observed. Therefore, clonidine in this combination is not recommended.

Tablets 0.075 mg, 0.15 mg

This product contains 205.5 mg of Lactose per maximum recommended daily dose.
Patients with the rare hereditary conditions of galactose intolerance
e.g. galactosaemia should not take this medicine.

Interactions

The reduction in blood pressure induced by clonidine can be further potentiated by concurrent administration of other hypotensive agents. This can be of therapeutic use in the case of other antihypertensive agents such as diuretics, vasodilators, beta-receptor blockers, calcium antagonists and ACE-inhibitors, but not alpha1-blocking agents.

Substances which raise blood pressure or induce a Na⁺ and water retaining effect such as non steroidal anti inflammatory agents can reduce the therapeutic effect of clonidine.

Substances with alpha2-receptor blocking properties such as phentolamine or tolazoline may abolish the alpha2-receptor mediated effects of clonidine in a dose-dependent manner.

Concomitant administration of substances with a negative chronotropic or dromotropic effect such as beta-receptor blockers or digitalis glycosides can cause or potentiate bradycardic rhythm disturbances.

It cannot be ruled out that concomitant administration of a beta-receptor blocker will cause or potentiate peripheral vascular disorders.

The antihypertensive effect of clonidine may be reduced or abolished and orthostatic regulation disturbances may be provoked or aggravated by concomitant administration of tricyclic antidepressants or neuroleptics with alpha-receptor blocking properties.

Based on observations in patients in a state of alcoholic delirium it has been suggested that high intravenous doses of clonidine may increase the arrhythmogenic potential (QT-prolongation, ventricular fibrillation) of high intravenous doses of haloperidol. Causal relationship and relevance for antihypertensive treatment have not been established.

The effects of centrally depressant substances or alcohol can be potentiated by clonidine.

Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of clonidine in pregnant women.

During pregnancy Catapres®, as any drug, should only be administered if clearly needed. Careful monitoring of mother and child is recommended.

Clonidine passes the placental barrier and may lower the heart rate of the foetus. There is no adequate experience regarding the long-term effects of prenatal exposure.

During pregnancy the oral forms of clonidine should be preferred. Intravenous injection of clonidine should be avoided.

Non-clinical studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section Toxicology).

Post partum a transient rise in blood pressure in the newborn cannot be excluded.

Lactation

Clonidine is excreted in human milk. However, there is insufficient information on the effect on newborns. The use of Catapres® is therefore not recommended during breast feeding.

Fertility

No clinical studies on the effect on human fertility have been conducted with clonidine. Non-clinical studies with clonidine indicate no direct or indirect harmful effects with respect to the fertility index (see section Toxicology).

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

However, patients should be advised that they may experience undesirable effects such as dizziness, sedation and accommodation disorder during treatment with Catapres®. Therefore, caution should be recommended when driving a car or operating machinery. If patients experience the above mentioned side effects they should avoid potentially hazardous tasks such as driving or operating machinery.

Side Effects

Most adverse effects are mild and tend to diminish with continued therapy.

Adverse events have been ranked under headings of frequency using the following convention:

Very common	≥ 1/10
Common	≥ 1/100, <1/10
Uncommon	≥ 1/1000, <1/100
Rare	≥ 1/10000, <1/1000
Very rare	<1/10000
Not known	Cannot be estimated from the available data

Endocrine disorders:

Gynaecomastia	rare
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Psychiatric disorders:

Confusional state	not known
Delusional perception	uncommon
Depression	common
Hallucination	uncommon
Libido decreased	not known
Nightmare	uncommon
Sleep disorder	common

Nervous system disorders:

Dizziness	very common
Headache	common
Paraesthesia	uncommon
Sedation	very common

Eye disorder:

Accommodation disorder	not known
Lacrimation decreased	rare

Cardiac disorders:

Atrioventricular block	rare
Bradycardia	not known
Sinus bradycardia	uncommon

Vascular disorders:

Orthostatic hypotension	very common
Raynaud's phenomenon	uncommon

Respiratory, thoracic and mediastinal disorders:

Nasal dryness	rare
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Gastrointestinal disorders:

Colonic pseudo-obstruction	rare
Constipation	common
Dry mouth	very common
Nausea	common
Salivary gland pain	common
Vomiting	common

Skin and subcutaneous tissue disorders:

Alopecia	rare
Pruritus	uncommon
Rash	uncommon
Urticaria	uncommon

Reproductive system and breast disorders:

Erectile dysfunction	common
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General disorders and administration site conditions:

Fatigue	common
Malaise	uncommon

Investigations:

Blood glucose increased	rare
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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the following telephone: +62 21 21684084 or email: IDSafety@zelligpharma.com; and via the national reporting system (e-meso.pom.go.id) and/or to pv-center@pom.go.id.

OverdoseSymptoms

Clonidine has a wide therapeutic range. Manifestations of intoxication are due to generalised sympathetic depression and include pupillary constriction, lethargy, bradycardia, hypotension, hypothermia, somnolence including coma, respiratory depression including apnoea. Paradoxical hypertension caused by stimulation of peripheral alpha1-receptors may occur.

Treatment

Careful monitoring and symptomatic measures.

Pharmacological Properties

Clonidine acts primarily on the central nervous system, resulting in reduced sympathetic outflow and a decrease in peripheral resistance, renal vascular resistance, heart rate, and blood pressure. Renal blood flow and glomerular filtration rate remain essentially unchanged. Normal postural reflexes are intact and therefore orthostatic symptoms are mild and infrequent.

During long-term therapy, cardiac output tends to return to control values, while peripheral resistance remains decreased. Slowing of the pulse rate has been observed in most patients given clonidine, but the drug does not alter normal hemodynamic response to exercise.

Pharmacokinetics

Absorption and distribution

The pharmacokinetics of clonidine is dose-proportional in the range of 75 – 300 mcg Clonidine, the active ingredient of Catapres®, is well absorbed and undergoes a minor first pass effect. Peak plasma concentrations are reached within 1 – 3 h after oral administration. The plasma protein binding is 30 – 40 %.

Clonidine is rapidly and extensively distributed into tissues, and crosses the blood-brain-barrier as well as the placental barrier. Clonidine is excreted in human milk. However, there is insufficient information on the effect on newborns.

Metabolism and elimination

The terminal elimination half-life of clonidine has been found to range from 5 to 25.5 hours. It can be prolonged in patients with severely impaired renal function up to 41 hours.

About 70 % of the dose administered is excreted with the urine mainly in form of the unchanged parent drug (40 – 60 % of the dose). The main metabolite p-hydroxy-clonidine is pharmacologically inactive. Approx. 20 % of the total amount is excreted with the faeces.

The pharmacokinetics of clonidine is not influenced by food nor by the race of the patient. The antihypertensive effect is reached at plasma concentrations between about 0.2 and 2.0 ng/mL in patients with normal renal function.

The hypotensive effect is attenuated or decreases with plasma concentrations above 2.0 ng/mL.

Toxicology

Single dose toxicity studies with clonidine were performed in different animal species by oral and parenteral routes of administration. The approximate oral LD50 values were 70 mg/kg (mouse), 190 mg/kg (rat), > 15 mg/kg (dog), and 150 mg/kg in monkeys. Following subcutaneous injection, the LD50 values were > 3 mg/kg in dogs and 153 mg/kg in rats. After intravenous administration the lethal dose ranges were between 6 mg/kg (dog) and < 21 mg/kg (rat).

Toxic trans-species signs of toxicity following exposure to clonidine were exophthalmus, ataxia and tremor, independently from the route of administration. At lethal doses, tonic-clonic convulsions occurred. In addition, excitement and aggressiveness alternating with sedation (mouse, rat, dog), salivation and tachypnea (dog) as well as hypothermia and apathy (monkey) were observed.

In repeated oral dose toxicity studies up to 18 months clonidine was well tolerated at 0.1 mg/kg (rat), 0.03 mg/kg (dog) and 1.5 mg/kg (monkey). In a 13 week study in rats, the no adverse effect level (NOAEL) was 0.05 mg/kg following subcutaneous administration. After intravenous administration rabbits and dogs tolerated 0.01 mg/kg/day for 5 and 4 weeks, respectively. Higher dosages caused hyperactivity, aggression, reduced food consumption and body weight gain (rat), sedation (rabbit) or an increase in heart and liver weight accompanied by elevated serum GPT, alkaline phosphatase and alpha-globulin levels and focal liver necroses (dog).

There were no signs of any teratogenic potential after oral administration in mouse and rat at 2.0 mg/kg and rabbit at 0.09 mg/kg, or after s.c. (0.015 mg/kg, rat) and i.v. treatment (0.15 mg/kg, rabbit). In rats, increases in resorption rate were observed at oral dosage of > 0.015 mg/kg/day; however dependent on duration of dosing. Fertility in rats was not impaired up to 0.15 mg/kg. Doses up to 0.075 mg/kg did not affect the peri- and postnatal development of the progeny.

There was no mutagenic potential in the Ames test and micronucleus assay in mice. Clonidine was not tumorigenic in a carcinogenicity assay in rats.

No local irritating or sensitizing potential was found in guinea pigs and rabbits following i.v. and i.a. administrations.

Availability

Tablet of Catapres® 0.075 mg Reg. No.: DK12492600710A1

Box contains 10 blisters of 10 tablets

Tablet of Catapres® 0.150 mg Reg. No.: DK12492600710B1

Box contains 10 blisters of 10 tablets

Store in temperature below 30 °C.

Store in a safe place, out of reach of children.

Only on doctor's prescription.

Hanya dengan resep dokter.

Manufactured, Packed and Released by:

Delpharm Reims France S.A.S

Reims – France for Glenwood GmbH, Germany

Registered by:

PT. Tunggal Idaman Abdi

Jl. Jend. Ahmad Yani No. 7

Jakarta 13230, Indonesia

Catapres®

75 mikrogram atau 150 mikrogram

(klonidin hidroklorida)

Bacalah keseluruhan brosur ini dengan saksama sebelum Anda mulai mengonsumsi obat ini.

- Simpan brosur ini. Mungkin diperlukan untuk dibaca kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, hubungi dokter atau apoteker.
- Obat ini diresepkan untuk Anda. Jangan berikan kepada orang lain karena dapat membahayakan mereka, meskipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika ada efek samping yang mengganggu atau serius, atau jika Anda mengalami efek samping yang tidak tercantum dalam brosur ini, harap beri tahu dokter atau apoteker.

Dalam brosur ini berisi:

1. Tablet CATAPRES dan kegunaannya
2. Hal-hal perlu diketahui sebelum mengonsumsi Tablet CATAPRES
3. Cara mengonsumsi Tablet CATAPRES
4. Efek samping yang mungkin terjadi
5. Cara menyimpan Tablet CATAPRES
6. Informasi lebih lanjut

1. TABLET CATAPRES DAN KEGUNAANNYA

Tablet CATAPRES berisi zat aktif klonidin. Obat ini termasuk dalam kelompok obat antihipertensi.

CATAPRES digunakan untuk menurunkan tekanan darah tinggi (untuk mengobati hipertensi).

2. HAL-HAL YANG PERLU DIKETAHUI SEBELUM MENGONSUMSI TABLET CATAPRES

Jangan konsumsi CATAPRES bila Anda:

- Sedang hamil, kemungkinan akan hamil, atau sedang menyusui
- Alergi (hipersensitif) terhadap klonidin atau bahan lain dalam CATAPRES (lihat bagian 6: Informasi lebih lanjut)
- Mengalami detak jantung lambat karena masalah jantung

Jangan konsumsi obat ini jika salah satu kondisi di atas terjadi pada Anda. Jika Anda tidak yakin, konsultasikan dengan dokter atau apoteker sebelum mengonsumsi CATAPRES.

Berhati-hatilah saat menggunakan CATAPRES

Konsultasikan dengan dokter atau apoteker sebelum mengonsumsi CATAPRES bila Anda:

- Mengalami gangguan jantung atau ginjal
- Mengalami atau pernah mengalami depresi
- Mengalami sembelit
- Mengalami gangguan saraf yang menyebabkan tangan dan kaki Anda terasa berbeda ('perubahan sensasi') atau tekanan darah rendah saat Anda berdiri

Jika Anda tidak yakin salah satu kondisi di atas terjadi pada Anda, konsultasikan dengan dokter atau apoteker sebelum mengonsumsi CATAPRES.

Konsumsi CATAPRES dapat menyebabkan mata kering, hal ini dapat menjadi masalah jika Anda memakai lensa kontak.

Mengonsumsi obat lain

Harap beri tahu dokter atau apoteker jika Anda sedang mengonsumsi atau akhir-akhir ini mengonsumsi obat lain, termasuk obat yang Anda beli tanpa resep dan obat herbal. Hal ini karena CATAPRES dapat memengaruhi cara kerja beberapa obat atau beberapa obat dapat memengaruhi cara kerja CATAPRES.

Secara khusus, beri tahu dokter atau apoteker jika Anda mengonsumsi salah satu obat berikut:

- Obat yang membuat Anda mengantuk
- Obat Antiinflamasi Nonsteroid (NSAID) seperti ibuprofen
- Obat antidepresan trisiklik atau neuroleptik dengan sifat penghambat reseptor alfa

Harap beri tahu dokter atau apoteker jika Anda mengonsumsi salah satu obat untuk tekanan darah tinggi atau gangguan jantung lainnya sebagai berikut:

- Beta blocker seperti atenolol
- Diuretik seperti furosemide
- Alpha blocker seperti prazosin atau doxazosin. Obat ini juga dapat digunakan untuk mengatasi gangguan prostat pada pria
- Zat penghambat reseptor alfa2 seperti fentolamin atau tolazolin dapat menghilangkan efek klonidin dengan perantara reseptor alfa2 bergantung pada dosis.
- Vasodilator seperti diazoksida atau natrium nitroprusida
- Antagonis kalsium seperti verapamil atau diltiazem hidroklorida
- Inhibitor ACE seperti kaptopril atau lisinopril
- Glikosida digitalis seperti digoksin

Jika Anda tidak yakin apakah salah satu dari obat di atas berlaku untuk Anda, konsultasikan dengan dokter atau apoteker sebelum mengonsumsi CATAPRES.

Tes

Jika Anda menjalani tes darah, beri tahu kepada petugas bahwa Anda mengonsumsi obat ini.

Operasi

Jika Anda akan menjalani operasi, lanjutkan mengonsumsi Tablet CATAPRES. Jika Anda perlu dirawat di rumah sakit, bawalah tablet tersebut bersama Anda.

Mengonsumsi CATAPRES dengan makanan dan minuman

Anda mungkin merasa mengantuk saat mengonsumsi CATAPRES. Minum alkohol saat mengonsumsi CATAPRES dapat memperburuk kondisi ini.

Kehamilan dan menyusui

Jangan mengonsumsi CATAPRES jika Anda sedang hamil, akan hamil, atau sedang menyusui.

Mengemudi atau menggunakan mesin

Anda mungkin merasa mengantuk, pusing, atau mengalami gangguan penglihatan. Jika mengalaminya, Anda tidak boleh mengemudi, mengoperasikan mesin, atau melakukan aktivitas apa pun yang dapat membahayakan Anda atau orang lain.

Informasi penting tentang kandungan CATAPRES

CATAPRES mengandung laktosa (sejenis gula). Jika dokter memberi tahu bahwa Anda tidak dapat menoleransi atau mencerna beberapa gula, konsultasikan dengan dokter sebelum mengonsumsi obat ini.

3. CARA MENGONSUMSI TABLET CATAPRES

Selalu konsumsi CATAPRES sesuai petunjuk dokter. Anda harus berkonsultasi dengan dokter atau apoteker jika tidak yakin.

Dokter akan memulai dengan dosis rendah dan meningkatkannya secara bertahap. Hal ini bergantung pada seberapa baik obat bekerja untuk mengendalikan tekanan darah.

Cara konsumsi CATAPRES

- Minum obat ini melalui mulut
- Jika perlu, dokter akan meningkatkan dosis secara bertahap
- Dosis harian awal untuk hipertensi ringan hingga sedang yaitu 0,075 mg hingga 0,150 mg dua kali sehari sudah cukup dalam kebanyakan kasus.
- Setelah jangka waktu 2 - 4 minggu, dosis dapat ditingkatkan jika perlu hingga respon yang diinginkan tercapai.
- Pada hipertensi berat, mungkin diperlukan peningkatan dosis tunggal lebih lanjut hingga 0,3 mg; dapat diulangi hingga tiga kali sehari (0,9 mg).

Populasi Pediatrik:

Tidak terdapat bukti yang cukup untuk penggunaan klonidin pada anak-anak dan remaja di bawah 18 tahun. Oleh karena itu, penggunaan klonidin tidak dianjurkan pada populasi pediatrik di bawah 18 tahun.

Jika Anda mengonsumsi CATAPRES lebih dari yang seharusnya

Jika Anda mengonsumsi CATAPRES lebih dari yang seharusnya, laporkan ke dokter atau segera pergi ke rumah sakit. Bawalah kemasan obat, meskipun tidak ada tablet yang tersisa.

Jika Anda lupa mengonsumsi CATAPRES

Jika Anda lupa mengonsumsi satu dosis, minumlah segera setelah Anda mengingatnya. Namun, jika mendekati waktu untuk dosis berikutnya, lewati dosis yang terlupa. Jangan minum dosis ganda untuk mengganti dosis yang terlupakan.

Jika Anda berhenti mengonsumsi CATAPRES

Jangan berhenti mengonsumsi CATAPRES tanpa terlebih dahulu berkonsultasi dengan dokter Anda. Jika Anda telah menggunakan obat ini untuk waktu yang lama, Anda mungkin merasa gelisah saat berhenti meminumnya. Ini disebut 'efek putus obat'.

Jika Anda memiliki pertanyaan lebih lanjut tentang konsumsi CATAPRES, tanyakan kepada dokter atau apoteker.

4. EFEK SAMPING YANG MUNGKIN TERJADI

Seperti semua obat, CATAPRES dapat menimbulkan efek samping, meskipun tidak semua orang mengalaminya.

Efek samping yang dijelaskan di bawah ini telah dialami oleh orang yang mengonsumsi CATAPRES.

Sebagian besar efek samping bersifat ringan dan cenderung berkurang dengan terapi yang berkelanjutan.

Efek samping telah diurutkan berdasarkan frekuensi kejadian sesuai ketentuan berikut:

Sangat umum	≥ 1/10
Umum	≥ 1/100, < 1/10
Tidak umum	≥ 1/1000, < 1/100
Jarang	≥ 1/10000, < 1/1000
Sangat jarang	< 1/10000
Tidak diketahui	Tidak dapat diperkirakan dari data yang ada

Gangguan endokrin:

Ginekomastia	jarang
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Gangguan kejiwaan:

Kondisi kebingungan	tidak diketahui
Persepsi delusi	tidak umum
Depresi	umum
Halusinasi	tidak umum
Libido menurun	tidak diketahui
Mimpi buruk	tidak umum
Gangguan tidur	umum

Gangguan sistem saraf:

Pusing	sangat umum
Sakit kepala	umum
Parestesia	tidak umum
Sedasi	sangat umum

Gangguan mata:

Gangguan akomodasi	tidak diketahui
Lakrimasi menurun	jarang

Gangguan jantung:

Blok atrioventrikular	jarang
Bradiaritmia	tidak diketahui
Sinus bradikardia	tidak umum

Gangguan pembuluh darah:

Hipotensi ortostatik	sangat umum
Fenomena Raynaud	tidak umum

Gangguan pernapasan, toraks, dan mediastinum:

Hidung kering	jarang
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Gangguan gastrointestinal:

Obstruksi semu kolon	jarang
Konstipasi	umum
Mulut kering	sangat umum
Mual	umum
Nyeri kelenjar ludah	umum
Muntah	umum

Gangguan kulit dan jaringan subkutan:

Alopecia	jarang
Pruritus	tidak umum
Ruam	tidak umum
Urtikaria	tidak umum

Gangguan sistem reproduksi dan payudara:

Disfungsi ereksi	umum
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Gangguan umum dan tempat pemberian kondisi:

Kelelahan	umum
Malaise	tidak umum

Pemeriksaan:

Glukosa darah meningkat	jarang
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Pelaporan efek samping

Jika Anda mengalami efek samping, laporkan ke dokter, apoteker, atau perawat. Hal ini termasuk efek samping yang mungkin tidak tercantum dalam brosur ini. Pelaporan efek samping dapat dilakukan secara langsung melalui +62 21 21684084 atau IDSafety@zuelligpharma.com. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. CARA MENYIMPAN TABLET CATAPRES

Simpan di tempat yang aman, jauh dari jangkauan anak-anak.

Simpan pada suhu di bawah 30 °C.

Jangan konsumsi CATAPRES setelah tanggal kedaluwarsa yang tertera pada kemasan. Tanggal kedaluwarsa mengacu pada hari terakhir bulan tersebut.

6. INFORMASI LEBIH LANJUT

Kandungan CATAPRES

- Kandungan zat aktif di dalam CATAPRES adalah klonidin hidroklorida. Setiap tablet mengandung 75 atau 150 mikrogram.
- Bahan lainnya adalah: laktosa monohidrat, kalsium hidrogen fosfat (anhidrat), pati jagung, silika koloid (anhidrat), povidon, pati larut, dan asam stearat.

Tampilan dan isi kemasan CATAPRES

- Tablet CATAPRES 75 mikrogram berbentuk tablet pipih, berwarna putih, dan dicetak, dengan kode identifikasi IC/IC di satu sisi
- Tablet CATAPRES 150 mikrogram berbentuk tablet pipih, berwarna putih, dan dicetak, dengan kode identifikasi 15C/15C mg di satu sisi

Tablet CATAPRES tersedia dalam dus berisi 10 blister berisi 10 tablet

No. Reg.:

- Tablet CATAPRES 75 mikrogram : DK12492600710A1
- Tablet CATAPRES 150 mikrogram : DK12492600710B1

HARUS DENGAN RESEP DOKTER

Pemegang Izin Edar dan Produsen

Izin Edar untuk CATAPRES dipegang oleh:

PT. Tunggal Idaman Abdi

Jl. Jend. Ahmad Yani No.7
Jakarta 13230
Indonesia

dan tablet diproduksi oleh:

Delpharm Reims S.A.S. Reims - Perancis untuk
Glenwood GmbH, Jerman

Informasi untuk pengguna ini direvisi pada bulan April 2026.