

Brosur kemasan: Informasi untuk pengguna

Catapres® Ampul 150 mikrogram dalam 1 ml Larutan Injeksi (klonidin hidroklorida)

Bacalah keseluruhan brosur ini dengan saksama sebelum Anda mulai menggunakan 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. CATAPRES Ampul dan kegunaannya
2. Hal-hal perlu diketahui sebelum menggunakan CATAPRES Ampul
3. Cara menggunakan CATAPRES Ampul
4. Efek samping yang mungkin terjadi
5. Cara menyimpan CATAPRES Ampul
6. Informasi lebih lanjut

1. CATAPRES AMPUL DAN KEGUNAANNYA

Nama obat ini adalah CATAPRES Ampul 150 mikrogram dalam 1 ml Larutan Injeksi (disebut CATAPRES Ampul dalam brosur ini). Obat ini merupakan larutan injeksi.

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

CATAPRES digunakan untuk menurunkan tekanan darah tinggi dalam kasus krisis hipertensi (peningkatan cepat tekanan darah yang memerlukan perawatan segera).

2. HAL-HAL YANG PERLU DIKETAHUI SEBELUM MENGGUNAKAN CATAPRES AMPUL

Jangan gunakan CATAPRES Ampul 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
- Berusia di bawah 18 tahun

Jangan gunakan CATAPRES jika salah satu kondisi di atas terjadi pada Anda. Jika Anda tidak yakin, konsultasikan

dengan dokter atau apoteker sebelum menggunakan CATAPRES Ampul.

Berhati-hatilah saat menggunakan CATAPRES Ampul

Konsultasikan dengan dokter atau apoteker sebelum menggunakan CATAPRES bila Anda:

- Menderita gangguan jantung atau ginjal
- Menderita atau pernah menderita depresi
- Menderita sembelit
- Menderita gangguan saraf yang menyebabkan tangan dan kaki Anda terasa berbeda ('sensasi berubah')

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

Penggunaan 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 Ampul dapat memengaruhi cara kerja beberapa obat lain atau beberapa obat lain dapat memengaruhi cara kerja CATAPRES Ampul.

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

- Obat Antiinflamasi Nonsteroid (NSAID) seperti ibuprofen
- Antidepresan trisiklik seperti imipramin atau neuroleptik yang memiliki aktivitas penghambatan reseptor alfa seperti clozapin

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

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

Tes

Jika Anda menjalani tes darah, beri tahu kepada petugas yang melakukan tes bahwa Anda menggunakan CATAPRES karena obat ini dapat memengaruhi hasil yang berkaitan dengan hati.

Operasi

Jika Anda akan menjalani operasi, lanjutkan menggunakan CATAPRES Ampul.

Menggunakan CATAPRES Ampul dengan makanan dan minuman

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

Kehamilan dan menyusui

Jangan menggunakan CATAPRES Ampul jika Anda sedang hamil, akan hamil, atau sedang menyusui.

Mengemudi dan 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 Ampul

CATAPRES Ampul mengandung kurang dari 1 mmol natrium (23 mg) per 1 ml ampul, yang berarti pada dasarnya 'bebas natrium'.

3. CARA MENGGUNAKAN CATAPRES AMPUL

CATAPRES Ampul biasanya diberikan oleh dokter atau perawat. Jika diperlukan, ampul dapat diberikan secara parenteral hingga 4 kali sehari.

Dokter akan memulai dengan dosis rendah, tetapi dosisnya dapat ditingkatkan jika Anda membutuhkan lebih banyak obat untuk mengendalikan tekanan darah.

Menerima injeksi

- CATAPRES Ampul disuntikkan perlahan ke dalam pembuluh darah. Dosis 0,2 mcg/kg/menit direkomendasikan untuk infus intravena. Kecepatan infus tidak boleh melebihi 0,5 mcg/kg/menit untuk menghindari peningkatan tekanan darah sementara. Dosis yang digunakan tidak boleh lebih dari 0,15 mg per infus.

CATAPRES Ampul tidak direkomendasikan untuk anak-anak atau remaja di bawah usia 18 tahun.

Jika Anda menggunakan CATAPRES Ampul lebih dari yang seharusnya

Kecil kemungkinan Anda akan diberi obat ini lebih dari yang seharusnya. Namun, beri tahu dokter atau perawat jika Anda merasa telah diberi terlalu banyak.

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

4. EFEK SAMPING YANG MUNGKIN TERJADI

Seperti semua obat, CATAPRES Ampul dapat menimbulkan efek samping, meskipun tidak semua orang mengalaminya. Efek samping yang dijelaskan di bawah ini telah dialami oleh orang yang menggunakan 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

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
Sembelit	umum
Mulut kering	sangat umum
Mual	umum
Nyeri kelenjar ludah	umum
Muntah	umum

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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 kondisi tempat pemberian:

Kelelahan	umum
Malaise	tidak umum

Pemeriksaan:

Glukosa darah meningkat	jarang
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Pelaporan efek samping

Jika Anda mengalami efek samping, bicarakan dengan dokter, apoteker, atau perawat Anda. Hal ini termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini. Pelaporan efek samping dapat dilakukan secara langsung melalui +62 21 21684084 atau IDSafety@zuelligpharma.com. Dengan melaporkan efek samping Anda dapat membantu menyediakan informasi keamanan obat ini.

5. CARA MENYIMPAN CATAPRES AMPUL

Jauhkan dari jangkauan dan pandangan anak-anak.

Ampul tidak boleh disimpan di atas suhu 30 °C dan harus terlindungi dari cahaya.

Jangan gunakan CATAPRES Ampul setelah tanggal kedaluwarsa yang tertera pada label dan kemasan. Tanggal kedaluwarsa mengacu pada hari terakhir bulan tersebut.

6. INFORMASI LEBIH LANJUT**Kandungan CATAPRES Ampul**

- Kandungan zat aktif di dalam CATAPRES Ampul adalah klonidin hidroklorida. Setiap 1 ml ampul mengandung 150 mikrogram klonidin hidroklorida.
- Bahan lainnya dalam injeksi adalah: natrium klorida, air untuk injeksi, dan asam klorida.

Tampilan dan isi kemasan CATAPRES Ampul

CATAPRES Ampul merupakan ampul kaca bening yang berisi larutan jernih dan tidak berwarna.

CATAPRES Ampul tersedia dalam dus berisi 10 ampul.

No Reg.:

- CATAPRES Ampul 150 mikrogram:
DKI2565700343A1

HARUS DENGAN RESEP DOKTER**Pemegang Izin Edar dan Produsen**

Izin Edar untuk CATAPRES Ampul dipegang oleh:

PT. Tunggal Idaman Abdi

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

dan ampul diproduksi oleh:

Delpharm Dijon
6 Boulevard de l'Europe 21800 Quetigny
Prancis

Informasi untuk pengguna ini direvisi pada bulan Oktober 2025.

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Catapres®

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Clonidine hydrochloride

Composition

1 ampoule of 1 ml contains 0.150 mg 2,6-dichloro-N-2-imidazolidinylidenebenzenamine hydrochloride (= clonidine hydrochloride)

Excipients:

Sodium chloride, hydrochlorid acid

Product description

Clear, colourless solution.

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.

Ampoules

Subcutaneous or i.m. injection of an ampoule containing 0.150 mg CATAPRES should only be carried out in patients in a lying position.

A dosage of 0.2 mcg/kg/minute is recommended for i.v. infusion. The rate of infusion should not exceed 0.5 mcg/kg/minute to avoid transient blood pressure increase. No more than 0.15 mg should be used per infusion.

If necessary, ampoules can be administered parenterally up to 4 times daily.

This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule, i.e. essentially 'sodium-free'.

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.

Paediatric 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 paediatric 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.

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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 ADHD, serious adverse reactions, including death, have been observed. Therefore, clonidine in this combination is not recommended.

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 α_1 -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 α_2 -receptor blocking properties such as phentolamine or tolazoline may abolish the α_2 -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 α -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	$\geq 1/10$
Common	$\geq 1/100, < 1/10$
Uncommon	$\geq 1/1000, < 1/100$
Rare	$\geq 1/10000, < 1/1000$
Very rare	$< 1/10000$
Not known	Cannot be estimated from the available data

Endocrine disorders:

Gynaecomastia rare

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 disorders:

Accommodation disorder not known
Lacrimation decreased rare

Cardiac disorders:

Atrioventricular block rare
Bradyarrhythmia not known
Sinus bradycardia uncommon

Vascular disorders:

Orthostatic hypotension very common
Raynaud's phenomenon uncommon

Respiratory, thoracic and mediastinal disorders:

Nasal dryness rare

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

General disorders and administration site conditions:

Fatigue common
Malaise uncommon

Investigations:

Blood glucose increased rare

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@zuelligpharma.com; and via the national reporting system (e-meso.pom.go.id) and/or to pv-center@pom.go.id.

Overdose

Symptoms

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 α_1 -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.

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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

Ampoule of CATAPRES 150 mcg/ml

Reg. No. DKI2565700343A1

Box contains 10 ampoules of 1 ml

Store in temperature below 30 °C.

Protect from light.

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

Only on doctor's prescription.

Hanya dengan resep dokter.

Manufactured by:

Delpharm Dijon

6 Boulevard de l'Europe 21800 Quetigny

France

Registered by:

PT. Tunggal Idaman Abdi

Jl. Jend. Ahmad Yani No.7

Jakarta 13230, Indonesia