

AMLOPIN TABLET 5MG

Amlodipine besylate eq. to amlodipine 5mg

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What Amlopin is used for

For the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, α -blockers, β -adrenoceptor blocking agent, or angiotensin-converting enzyme inhibitor.

How Amlopin work

Amlodipine is a calcium channel blocker. It works by relaxing blood vessels, so that blood passes through them more easily. It also improves blood supply to the heart muscle, which then receives more oxygen.

Before you use Amlopin

When you must not take it

Do not take amlodipine

- if you are allergic to amlodipine or similar calcium antagonists (which are called dihydropyridine derivatives).
- if you have very low blood pressure.
- if you are suffering from insufficient blood supply to your tissues with symptoms such as low blood pressure, low pulse, fast heartbeat (shock, including cardiogenic shock-due to severe heart troubles).
- if you are suffering from narrowing of the artery which takes blood away from the heart (aortic stenosis).
- if you have unstable heart failure after acute heart attack.

Before you start to take it

Tell your doctor before you start:

- if you have heart failure.
- if you have reduced liver/renal function.

Use in patients with heart failure: Amlodipine was associated with increased reports of pulmonary edema despite no significant difference in the

incidence of worsening heart failure as compared to placebo.

Use in patients with reduced hepatic function

As with all calcium antagonists, amlodipine half-life is prolonged in patients with impaired liver function and dosage recommendations have not been established. The drug should therefore be administered with caution in these patients.

Amlodipine is unlikely to impair a patient's ability to drive or use machinery.

Taking other medications

Amlodipine has been safely administered with thiazide diuretics, alpha blockers, beta blockers, aluminium/magnesium antacid, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerine, non-steroidal anti-inflammatory drugs, antibiotics, cimetidine, atorvastatin, digoxin, ethanol, warfarin, cyclosporin and oral hypoglycemic drugs. Administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects.

How to take Amlopin

How much to take

Usual adult dose: 5mg amlodipine once daily, which may be increased to a maximum dose of 10mg. Use in the elderly: Normal dosage regimens are recommended. Use in children: Safety and effectiveness have not been established. Use in patients with impaired hepatic function: The drug should be administered with caution.

Use in renal failure: Amlodipine may be used in such patients at normal doses.

When to take it

Always take amlodipine exactly as your doctor has told you.

How long to take it

You should check with your doctor or pharmacist.

If you forget to take it

Do not take a double dose to make up for a forgotten tablet.

If you take too much (overdose)

If taken too much amlodipine, contact your doctor, an emergency department or a poisoning center immediately. The person concerned should be made to lie down with their arms and legs up (resting on a couple of cushions). Symptoms of an overdose are: extreme

dizziness and/or feeling very light headed.

While you are using Amlopin

Things you must do

Inform doctor of medications you are taking.

Things you must not do

You must take your medication as directed.

Things to be careful of

If you are pregnant or become pregnant or breast-feeding during treatment, you should not take amlodipine unless your doctor tells you to. This is because the risk to your unborn baby is not yet known.

Side effects

Amlodipine is well tolerated. The most common observed side effects were: Headache, dizziness, sleepiness, feeling the heartbeat, flushing, abdominal pain, nausea, edema and fatigue. Less common observed side effects include: Reduction in white blood cells, blood platelets, which increases risk of bleeding or bruising, high blood sugar, difficulty in sleeping, mood changes, increase in muscle tension, reduced sense of touch, tingling or numbness in hands or feet, nerve disorder which causes weakness, tingling or numbness, fainting, taste perversion, shaking, visual disturbances, ringing in the ears, low blood pressure, inflammation of blood vessels often with skin rash, cough, shortness of breath, swelling and irritation inside the nose, altered bowel habits, dry mouth, indigestion (including gastritis), swelling of gums, inflammation of pancreas which causes severe pain in the abdomen and back, vomiting, hair loss, increased sweating, bruise like spots on skin and itching rash.

After using Amlopin

Storage

Store in cool, dry place below 30°C. Protect from light. Keep out of reach of children.

Disposal

Ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like?

White, top-scored, hexagonal-shaped tablet.

Ingredients

amlodipine besylate, microcrystalline cellulose, tricalcium phosphate, croscarmellose sodium, magnesium stearate
MAL NO: MAL06111336A

Manufacturer

Prime Pharmaceutical Sdn. Bhd.
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Taman Perindustrian Bukit Tengah
14000 Bukit Mertajam, Penang, Malaysia.

Marketing Authorization Holder

Prime Pharmaceutical Sdn. Bhd.
Penang, Malaysia.

Date of revision

27-09-2011

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Apakah yang ada pada risalah ini

- Apakah kegunaan *Amlopin*
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- Cara menggunakan *Amlopin*
- Semasa menggunakan *Amlopin*
- Kesan-kesan sampingan
- Cara penyimpanan dan pelupusan *Amlopin*
- Maklumat lanjut
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Apakah kegunaan *Amlopin*

Sebagai rawatan pertama penyakit tekanan darah tinggi, secara rawatan tunggal dalam kawalan tekanan darah sebahagian besar pesakit. Penyakit tekanan darah tinggi yang tidak terkawal dengan agen tunggal antihipertensif lain boleh ditambah dengan amlodipine, yang pernah digunakan sebagai kombinasi dengan diuretik thiazid, ubat penghalang alpha atau beta, atau perencat enzim penukaran angiotensin.

Bagaimana *Amlopin* berfungsi

Amlodipine adalah penghalang terusan kalsium. Ia mengendurkan saluran darah supaya darah mengalir dengan senang. Ia menambah darah ke otot jantung supaya lebih oksigen.

Sebelum mengambil *Amlopin*

Bila tidak boleh mengambil

Jangan mengambil amlodipine:

- jika alergik kepada amlodipine atau antagonis kalsium lain yang sama. (derivasi dihidropiridin).
- jika tekanan darah sangat rendah.
- jika mengalami kekurangan bekalan darah tisu seperti tekanan darah rendah, nadi rendah, denyutan jantung cepat(kejutan, termasuk kejutan jantung sebab masalah serius jantung).
- jika mengalami kesempitan arteri yang membawa darah keluar dari jantung (stenosis aorta).
- jika kegagalan jantung tak stabil selepas serangan jantung akut.

Sebelum mula mengambil

Beritahu doktor sebelum memulakan rawatan:

- jika ada kegagalan jantung.
- jika ketidaksempurnaan fungsi ginjal dan hati. Untuk pesakit dengan kegagalan jantung: Amlodipine adalah dikaitkan dengan laporan edema paru-paru walaupun tiada perbezaan jelas dengan plasebo berlakunya kejadian

buruk kegagalan jantung. Untuk pesakit dengan ketidaksempurnaan fungsi ginjal dan hati: Kesan amlodipine bertambah di golongan pesakit ini. Ubat digunakan dengan berhati-hati kerana tiada maklumat cara pendosan. Amlodipine sepatutnya tidak mengganggu keupayaan memandu dan mengendalikan mesin.

Jika mengambil ubat-ubat lain

Amlodipine pernah digunakan dengan diuretik thiazid, penghalang alpha dan beta, antasid aluminium/magnesium, perencat enzim penukaran angiotensin, nitrat tindak lama, nitroglycerin bawah lidah, ubat antiradang bukan steroid, antibiotik, cimetidin, atorvastatin, digoksin, etanol, warfarin, siklosporin dan ubat hipoglisemia oral.

Administrasi bersama dengan buah limau gedang atau jusnya tidak sesuai kerana penyerapan ubat meningkat untuk setengah golongan pesakit lalu mengakibatkan peningkatan kesan penurunan tekanan darah ubat.

Cara menggunakan *Amlopin*

Berapa banyak harus diambil

Dewasa: 5mg amlodipine setiap hari,

boleh ditambah sehingga dos

maksimum 10mg. Untuk pesakit tua:

Dos biasa. Untuk kanak-kanak:

Keselamatan dan keberkesanan belum

diketahui. Pesakit ketidaksempurnaan

fungsi hati: Ubat perlu diadministrasi

dengan berhati-hati. Pesakit dengan

ketidaksempurnaan fungsi ginjal:

Amlodipine dalam dos biasa.

Bila perlu diambil

Ambil amlodipine mengikut arahan

oleh doktor.

Berapa lama perlu diambil

Perlu mengikut nasihat doktor atau

ahli farmasi.

Jika terlupa mengambil

Jangan mengambil dos berganda

sebagai gantian dos yang terlepas.

Jika mengambil berlebihan(terlebih

dos)

Jika terlebih dos, hubungi doktor,

jabatan kecemasan atau pusat racun

dengan segera. Pesakit perlu berbaring

dengan tangan dan kaki disokong naik

(seperti atas beberapa buah kusyen).

Tanda-tanda lebih dos: pening kuat

dan/atau pening-pening lambat.

Semasa menggunakan *Amlopin*

Perkara yang perlu dilakukan

Beritahu doktor ubat yang sedang

diambil.

Perkara yang tidak boleh dilakukan
Pengambilan ubat mestilah seperti yang diarahkan.

Perkara yang perlu diberi perhatian

Beritahu doktor jikalau hamil atau penyusuan semasa rawatan, amlodipine tidak boleh diambil tanpa arahan doktor. Ini adalah kerana tiada maklumat mengenai risiko kepada bayi dalam kandungan.

Kesan-kesan sampingan

Paling biasa: sakit kepala, pening, mengantuk, terasa denyutan nadi, sakit abdomen, loya, edema dan keletihan. Kurang berlaku: kekurangan sel darah putih dan sel pembeku meningkatkan risiko pendarahan dan lebam, paras gula darah tinggi, tidak lena, perubahan emosi, ketegangan otot, pengurangan deria rasa, rasa kebas tangan dan kaki, gangguan saraf mengakibatkan kelemahan dan rasa kebas, pangsang, perubahan rasa, gigil, gangguan penglihatan, desiran telinga, tekanan darah rendah, inflamasi saluran darah, batuk, penat, iritasi hidung, kering mulut, kurang penghadaman(termasuk inflamasi gastrik), bengkak gusi, inflamasi pancreas menyebabkan sakit abdomen dan belakang, muntah, gugur rambut, peluh, lebam kulit dan gatal-gatal.

Cara penyimpanan dan pelupusan *Amlopin*

Penyimpanan

Simpan di tempat yang dingin dan

kering, bawah 30°C. Jauhkan dari

cahaya. Jauhkan dari kanak-kanak.

Pelupusan

Dapatkan nasihat ahli farmasi cara pelupusan ubat yang ingin dibuang.

Maklumat lanjut

Rupa dan warna produk

Tablet putih berbentuk segienam dan permukaan atas skor.

Bahan-bahan kandungan

Selulos mikrokrystalin, trikalsium

fosfat, sodium kroskarmelo dan

magnesium stearat.

MAL NO: MAL06111336A

Pengilang

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Malaysia.

Tarikh kemaskini RiMUP

27-09-2011

Pemegang pendaftaran keluaran

Prime Pharmaceutical Sdn. Bhd.

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