

# METHYLDOPA TABLET 250 mg®

METHYLDOPA TABLET 250 mg

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## What Methyldopa Tablet 250 mg is used for

Methyldopa Tablet 250 mg is indicated in the treatment of moderate to severe high blood pressure, including that implicated by kidney disease.

## How Methyldopa Tablet 250 mg works

Methyldopa Tablet 250 mg contains methyldopa which belongs to a group of medicines which lower blood pressure.

## Before you use Methyldopa Tablet 250 mg

Methyldopa Tablet 250 mg should not be used if:

Allergic to any ingredient of the tablet, have liver disease, have high blood pressure due to a tumour near the kidney, suffer from depression or taking MAOIs (monoamine oxidase inhibitors) drugs for depression.

Before starting use of Methyldopa Tablet 250 mg tell your doctor or pharmacist if you have: liver disease, kidney disease, damaged or diseased blood vessels in your brain.

Please tell your doctor or pharmacist if you are taking alprostadil, non-steroidal anti-inflammatory drugs, diazepam or other psychotic drugs, oral contraceptive or hormone replacement therapy or other drugs such as levodopa, linezolid, MAOIs (monoamine oxidase inhibitors) drugs, moxisylyte (used to treat Raynaud's syndrome), muscle relaxants such as baclofen, nitrates such as glycerol trinitrate, steroids such as prednisolone, sympathomimetics medicines such as salbutamol, ulcers medicine such as carbenoxolone and iron supplement.

Date of revision:

September 19<sup>th</sup>, 2011

## How to take Methyldopa Tablet 250 mg

### How much to take

Always take the dose exactly as your doctor has told you.

### Adults and children over 12 years dosage:

Initially 250 mg two or three times a day for 2 days. Then increased every 2 or more days until an adequate response is achieved up to a maximum of 3 g daily.

### Children under 12 years dosage:

Initially 10 mg per kg of bodyweight daily in 2-4 divided doses adjusted as required up to 65 mg/kg or 3 g daily, whichever is less.

### Elderly dosage:

Initially not more than 250 mg per day, increasing up to a maximum of 2 g per day.

### How long to take it

Do not stop taking this medicine unless your doctor tells you to stop because the blood pressure may increase.

### If you forget to take it

If you miss a dose of Methyldopa Tablet 250 mg, take it as soon as possible. Unless if nearly time for next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

### If you take too much (overdose)

If you have taken more than the prescribed dose, contact your doctor or pharmacist. Overdose symptoms are drowsiness, weakness, slow heart rate, low blood pressure, dizziness, lightheadedness, painful infrequent bowel movements, bloated feeling, wind, diarrhoea, being sick.

## While you are using Methyldopa Tablet 250 mg

1. Do not suddenly stop taking the medicine.
2. Do not take more than the recommended dose.
3. You are advised to avoid alcohol.

### Side Effects

Side effects of Methyldopa Tablet 250 mg are sedation usually transient, low blood pressure causing dizziness, lightheadedness, and disease blood vessel in your brain. Severe chest pain may be aggravated.

Low blood pressure may occur. Slow heart rate, nose stuffiness, mild dryness, of mouth distension, constipation, flatus, diarrhea, nausea, and vomiting occur occasionally. Occasionally, drug related fever and abnormal liver function test, mild and reversible jaundice. Rare reaction include sore tongue, breast enlargement, lactation, impotence, skin rash, mild joint pain, muscle pain, parkinsonism, psychic disturbances including nightmares, depression and darkening of urine exposed to air after voiding.

## How to store and dispose

### Storage

Keep container tightly closed in a dry place, below 25°C. Protect from light. Keep out of the reach of children..

### Disposal

Do not dispose the medicine into wastewater or household garbage. Ask your pharmacist how to dispose of medicines that are no longer required.

## Product Description

### What it looks like?

Methyldopa Tablet 250 mg is round and yellow colored coated tablet. The pack sizes are: Plastic Container of 30 tablets and Blister pack of 10's.

### Ingredients

The active substance is methyldopa 250 mg per tablet.

The other ingredients of Methyldopa Tablet 250 mg are maize starch, povidone, magnesium stearate, D&C Yellow No 10, Ethanol 96%, stearic acid, polyvinyl acetate phthalate, hypromellose, titanium dioxide, cetyl alcohol, macrogol 4000, diethyl phthalate, isopropyl alcohol, chloroform, acetone, lactose, sodium starch glycolate and sorbitan oleate.

## Registration Numbers:

Methyldopa Tablet 250 mg :  
MAL19860172A

## Manufactured by:

Idaman Pharma Manufacturing Sdn Bhd  
(661901-P)  
Lot 24, Bakar Arang Industrial Estate,  
Sungai Petani, Kedah, Malaysia.

Marketing Authorisation Holder

IDAMAN PHARMA MANUFACTURING SDN BHD

# METHYLDOPA TABLET 250 mg®

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## Apakah yang ada pada risalah ini:

1. Apa kegunaan Methyldopa Tablet 250 mg
2. Bagaimana Methyldopa Tablet 250 mg berfungsi
3. Sebelum mengambil Methyldopa Tablet 250 mg
4. Cara pengambilan Methyldopa Tablet 250 mg
5. Semasa menggunakan Methyldopa Tablet 250 mg
6. Kesan-kesan sampingan
7. Cara penyimpanan dan pelupusan
8. Deskripsi produk

## Apa kegunaan Methyldopa Tablet 250 mg

Methyldopa Tablet 250 mg digunakan dalam rawatan tekanan darah tinggi yang sederhana dan teruk, termasuk yang dikaitkan dengan penyakit buah pinggang.

## Bagaimana Methyldopa Tablet 250 mg berfungsi

Methyldopa Tablet 250 mg mengandungi methyldopa yang tergolong dalam kumpulan ubat darah tinggi yang menurunkan tekanan darah menjadi lebih rendah.

## Sebelum mengambil Methyldopa Tablet 250 mg

Methyldopa Tablet 250 mg tidak boleh digunakan jika:

Alah kepada bahan mana-mana tablet, mempunyai penyakit hati, mempunyai tekanan darah tinggi disebabkan oleh tumor berhampiran buah pinggang, menderita akibat tekanan perasaan atau mengambil ubat MAOIs (inhibitor oxidase monoamine) untuk kemurungan.

Sebelum mula menggunakan Methyldopa Tablet 250 mg maklumkan kepada doktor atau ahli farmasi anda jika anda mempunyai penyakit hati, penyakit buah pinggang, saluran darah yang rosak atau berpenyakit di dalam otak.

Sila beritahu doktor atau ahli farmasi jika anda mengambil alprostadil, ubat bukan steroid anti-radang, diazepam atau ubat psikotik yang lain, kontraseptif oral atau terapi hormon gantian atau ubat lain seperti levodopa, linezolid, ubat MAOIs (inhibitor oxidase monoamine), moxisylyte (yang digunakan untuk merawat sindrom Raynaud), penenang otot seperti baclofen, nitrat seperti trinitrate gliserol, steroid seperti prednisolone, ubat 'sympathomimetics' seperti salbutamol,

ubat ulser seperti carbenoxolone dan 'iron supplement'.

## Cara pengambilan Methyldopa Tablet 250 mg

### Berapa banyak untuk diambil

Ambil dos mengikut arahan doktor.

### Dos dewasa dan kanak-kanak lebih 12 tahun:

Untuk permulaan, ambil 250mg dua atau tiga kali sehari selama 2 hari. Kemudian meningkat setiap 2 hari atau lebih sehingga tindak balas yang mencukupi dapat dicapai sehingga maksimum 3g setiap hari.

### Dos kanak-kanak dibawah 12 tahun:

Pada mulanya 10mg per kg berat badan sehari dalam 2-4 dos yang dibahagikan diselaraskan sebagaimana yang dikehendaki sehingga 65mg/kg atau 3g setiap hari, yang mana yang lebih kurang.

### Dos Warga Tua:

Pada mulanya tidak lebih daripada 250mg sehari, meningkat kepada maksimum 2g setiap hari.

### Berapa lama ubat diambil

Jangan berhenti minum ubat ini kecuali atas arahan doktor anda kerana tekanan darah boleh meningkat.

### Jika anda lupa mengambil ubat

Jika anda terlewat mengambil dos Methyldopa Tablet 250 mg, ambil ubat secepat mungkin. Kecuali jika hampir masa untuk dos berikutnya, lewatkannya dos tersebut dan kembali ke jadual dos rutin. Jangan mengambil 2 dos sekaligus.

### Jika anda mengambil ubat terlalu banyak

Jika anda mengambil dos lebih dari yang ditetapkan, hubungi doktor atau ahli farmasi anda. Tanda-tanda dos berlebihan adalah seperti mengantuk, lemah, denyut jantung lemah, tekanan darah rendah, pening, rasa ringan kepala, pergerakan usus menyakitkan dan tidak kerap, rasa kembung, angin, cirit-birit, rasa atau sakit.

## Semasa menggunakan Methyldopa Tablet 250 mg

1. Jangan berhenti mengambil ubat secara mendadak.
2. Jangan mengambil lebih dari dos yang disyorkan.
3. Anda dinasihatkan untuk mengelakkan pengambilan alkohol.

### Kesan-kesan sampingan

Kesan-kesan sampingan Methyldopa Tablet 250 mg ubat pelali biasanya sementara waktu, tekanan darah rendah

yang menyebabkan pening, rasa ringan kepala, dan penyakit saluran darah dalam otak. Sakit dada yang teruk mungkin menjadi lebih teruk. Tekanan darah rendah mungkin berlaku. Kadang-kadang, demam berkaitan dada dan ujian fungsi hati yang tidak normal, penyakit kuning. Tindak balas yang jarang berlaku termasuk sakit lidah, pembesaran payu dara, laktasi, mati pucuk, ruam kulit, sakit sendi yang ringan, sakit otot, tanda penyakit parkinson gangguan psikik termasuk mimpi buruk, kemurungan dan air kencing menjadi gelap setelah terdedah kepada udara.

## Cara penyimpanan dan pelupusan

### Penyimpanan

Simpan ke dalam bekas yang tertutup rapat dan diletak di tempat yang kering, dibawah suhu 25°C. Jauhi dari cahaya dan kanak-kanak.

### Pelupusan

Jangan buang ubat ke dalam longkang dan tong sampah. Bertanya kepada ahli farmasi anda cara membuang ubat yang tidak diperlukan lagi.

## Diskripsi produk

### Rupa dan warna tablet

Methyldopa Tablet 250 mg berbentuk bulat dan bersalut berwarna kuning. Saiz pek adalah: Botol plastik berisi 30 tablet dan Blister pek 10's.

### Bahan-bahan

Bahan aktif adalah methyldopa 250 mg per tablet.

Bahan-bahan lain dari Methyldopa Tablet 250 mg adalah kanji jagung, povidone, magnesium stearat, 'D & C Yellow No 10', Ethanol 96%, 'stearic acid', 'polyvinyl acetate phthalate', 'hypromellose', 'titanium dioxide', 'cetyl alcohol', 'macrogol 4000', 'diethyl phthalate', 'isopropyl alcohol', 'chloroform', 'acetone', laktosa, 'sodium starch glycolate' dan 'sorbitan oleate'.

### Nombor Pendaftaran:

Methyldopa Tablet 250 mg :  
MAL19860172A

### Dikilangkan oleh:

Idaman Pharma Manufacturing Sdn Bhd  
(661901-P)

Lot 24, Bakar Arang Industrial Estate,  
Sungai Petani, Kedah, Malaysia.

Tarikh semakan:

Pemegang Kuasa Pemasaran