

Package leaflet: Information for the user

Methyldopa

125 mg, 250 mg & 500 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Methyldopa Tablets are and what they are used for
2. What you need to know before you take Methyldopa Tablets
3. How to take Methyldopa Tablets
4. Possible side effects
5. How to store Methyldopa Tablets
6. Contents of the pack and other information

1. What Methyldopa Tablets are and what they are used for

The name of your medicine is Methyldopa 125 mg, 250 mg or 500 mg Tablets (referred to as Methyldopa Tablets throughout this leaflet).

Methyldopa Tablets contain the active ingredient methyldopa, which belongs to a group of medicines called antihypertensives, which lower blood pressure.

Methyldopa Tablets are used for the treatment of hypertension (high blood pressure).

2. What you need to know before you take Methyldopa Tablets

Do not take this medicine

- if you are allergic to methyldopa or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had liver disease
- if you have ever had depression
- if you have been taking a type of medicine called a monoamine oxidase inhibitor (MAOI)
- if you have high blood pressure due to a tumour near your kidney called 'phaeochromocytoma' or 'paraganglioma'
- If you have porphyria (a rare, inherited blood disorder).

If you are unsure if any of the above apply to you, please talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Methyldopa Tablets

- if you have a blood disorder called haemolytic anaemia
- if you have liver problems
- If you have jaundice (yellowing of the skin and eyes)
- if you have a fever
- If you have abnormal movements (involuntary).

Check with your doctor while taking this medicine if you are going to have:

- dialysis
- an operation
- a blood transfusion.

Other medicines and Methyldopa Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines obtained without a prescription, as some medicines may affect each other's action. This includes herbal medicines.

Do not take Methyldopa Tablets if you are taking a type of medicine called a 'monoamine oxidase inhibitor' (MAO inhibitor) used to treat depression.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- alprostadil used to treat erectile dysfunction
- NSAIDs (non-steroidal anti-inflammatory drugs) which are used to relieve pain
- medicines used to treat anxiety or insomnia (e.g. diazepam, temazepam)
- antihypertensive medicines such as beta-blockers or calcium-channel blockers or diuretics (also known as 'water tablets') used to treat high blood pressure (e.g. propranolol, nifedipine, verapamil or furosemide)
- corticosteroids (e.g. prednisolone, hydrocortisone)
- medicines to treat Parkinson's disease such as levodopa or entacapone

size: 160 x 450 mm

- moxisylyte, used to treat Raynaud's syndrome
- muscle relaxants such as baclofen, tizanidine
- nitrates (e.g. glycerol trinitrate "GTN", isosorbide dinitrate/mononitrate)
- combined oral contraceptive ("the pill") or hormone replacement therapy (HRT)
- lithium - used to treat some types of depression
- medicines called 'phenothiazines' such as chlorpromazine - used for mental illness and sometimes feeling and being sick
- medicines called 'tricyclic antidepressants' - used to treat depression
- sympathomimetics medicines used mainly for coughs and colds (e.g. ephedrine or salbutamol)
- iron and supplements containing iron, such as multivitamins with minerals.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Methyldopa Tablets.

Surgery

If you have to have surgery, including dental, that requires an anaesthetic, you must inform the dentist or hospital that you are taking Methyldopa Tablets.

Methyldopa Tablets with alcohol

You are advised not to drink alcohol while taking Methyldopa Tablets. Discuss this with your doctor if you have any questions.

Laboratory tests

Your doctor may do blood tests to check how your liver is working during the first 6 – 12 weeks. He or she may use similar tests if you have a fever at any time while you are taking methyldopa.

Tell your doctor that you are taking methyldopa if you are having a blood or urine test, as this medicine may affect the results of certain laboratory tests.

Rarely, in patients taking methyldopa, urine may darken when it is exposed to air after voiding.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.



Driving and using machines

You may feel drowsy or light-headed while taking Methyldopa Tablets. If this happens do not drive or use any tools or machines.

3. How to take Methyldopa Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should take this medicine by mouth and exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. It is important to continue taking Methyldopa Tablets for as long as your doctor has prescribed. Do not take more or less than your doctor has prescribed. The breakline is not intended for breaking the tablet.

Recommended dose

Adults

- The usual starting dose for the first two days is 250 mg two or three times a day
- Your doctor may then change your dose depending on how you respond
- You should not take more than 3000 mg in a day.

The elderly

- The usual starting dose will not be more than 250 mg each day
- Your doctor may then slowly increase the dose
- You should not usually take more than 2000 mg in a day.

Children

The doctor will work out the number of tablets.

The dose is based on the weight of the child.

- The usual starting dose is 10 mg for each kg of body weight each day
- This dose is taken in two to four doses during the day

• Your doctor may then change the dose depending on how the child responds

• A child will not usually take more than 65 mg for each kg (or 3000 mg a day), whichever is less.

If you take more Methyldopa Tablets than you should

If you realise that you have taken more Methyldopa Tablets than your doctor has recommended (or if someone else has taken some of your Methyldopa Tablets), contact your doctor right away. If you cannot contact your doctor, go to your nearest hospital casualty department and take the pack with you.

If you forget to take Methyldopa Tablets

If you forget to take a dose, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Methyldopa Tablets

Do not stop taking Methyldopa Tablets without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause unwanted side effects, although not everybody gets them.

Contact your doctor IMMEDIATELY if you have any of the following side effects as they are serious and require medical attention:

- an allergic reaction – symptoms such as shortness of breath, skin rash or itching, hives, swelling of your lips, face or tongue, chills or
- fever or painful joints
- chest pain, slow heart rate, existing angina made worse, problems with the electrical current in the heart (AV block)
- severe skin reactions (such as painful reddening, followed by blistering and peeling of layers of skin)
- liver problems, including jaundice and hepatitis - signs include yellowing of your skin and eyes, sometimes with a fever, pale stools and dark urine
- pain in the gut and diarrhoea caused by inflammation of the bowel (colitis)
- severe pain in the gut and back caused by inflammation of the pancreas (pancreatitis)
- reduction in red blood cells (anaemia) – this can make your skin pale and make you weak or breathless
- abnormal blood test causing symptoms such as pale skin, tiredness, fever and sore throat
- having movements you cannot control

The following reactions have also been reported:

Blood:

- bruising and prolonged bleeding after injury
- your medicine may alter the numbers and types of your blood cells and cause a rise in urea in the blood

Nervous system:

- feeling sleepy or tired - this may happen at the start of treatment or when the dose is increased, and usually goes away
- headache or feeling weak – this may happen at the start of treatment and usually goes away
- pins and needles
- Bells' Palsy (weakness or paralysis of the muscles on one side of the face)
- Parkinsonism – with symptoms such as tremor, a decrease in body movements with an inability to move your muscles
- confusion
- frequent dizziness or fainting
- dizziness due to low blood pressure and light-headedness (particularly when standing up quickly)

Nose and chest:

- nasal stuffiness

Stomach and gut:

- feeling sick
- being sick
- abdominal pain
- feeling bloated
- constipation
- excess wind
- diarrhoea
- dry mouth
- sore or black tongue

Skin and hair:

- skin rash or peeling skin

Joints and muscles:

- painful and/or swollen joints
- muscle pains

Infections:

- swelling of salivary glands

General:

- water retention causing swelling and weight gain
- fever

Sexual:

- breast enlargement

- breast development in men

- loss of periods in women

- abnormal production of milk

- changes in sexual function such as impotence and not being able to ejaculate

- decreased sex drive

Psychiatric:

- mental changes, including nightmares or depression
- delusions and paranoia - which will stop when you stop taking this medicine

Laboratory tests:

- Your doctor may need to carry out simple blood tests during the first few months of therapy with methyldopa. Results could show:
 - o a decrease in blood cell production
 - o an increase in some white blood cells
 - o abnormal levels of prolactin

Methyldopa Tablets may also interfere with the interpretation of certain blood and urine tests.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Methyldopa Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store in the original package.

Do not use this medicine after the expiry date that is stated on the carton or blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Methyldopa Tablets contain

Each film-coated tablet contains 125 mg, 250 mg or 500 mg of the active ingredient methyldopa (anhydrous).

The other ingredients are anhydrous citric acid, povidone, sodium starch glycollate, stearic acid, magnesium stearate, microcrystalline cellulose, hydroxypropylmethylcellulose, Opaspray Yellow M-1F-6047B solids (which includes titanium dioxide (E171), yellow iron oxide (E172) and Quinoline yellow (E104)).

What Methyldopa Tablets look like and contents of the pack

Methyldopa 125 mg Tablets are yellow, round, film coated tablets, embossed with "MT/125" separated by a breakline.

Methyldopa 250 mg Tablets are yellow, round, film coated tablets, embossed with "MT/250" separated by a breakline.

Methyldopa 500 mg Tablets are yellow, round, film coated tablets, embossed with "MT/500" separated by a breakline.

Methyldopa 125 mg, 250 mg and 500 mg Tablets are available in blister packs of 56 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Sovereign Medical, Sovereign House
Miles Gray Road, Basildon, Essex
SS14 3FR, UK

Manufacturer

Waymade Plc, Josselin Road,
Burnt Mills Industrial Estate,
Basildon, Essex SS13 1QF, UK

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PL 06464/1433 Methyldopa 250 mg Tablets

PL 06464/1434 Methyldopa 500 mg Tablets

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