

Package leaflet: Information for the user

METHYLDOPA 250MG AND 500MG 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 or nurse. 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 250mg or 500mg Tablets. It contains the active ingredient called methyldopa.

Methyldopa belongs to a group of medicines called antihypertensives, which lower blood pressure. Methyldopa tablets are used to treat high blood pressure (hypertension). It works by relaxing the blood vessels so that blood can flow more easily through the body.

2. What you need to know before you take Methyldopa Tablets**Do not take Methyldopa Tablets if you:**

- are allergic to methyldopa or any of the other ingredients of this medicine (listed in section 6)
- have **liver disease**
- suffer from depression
- are taking **MAOIs** (monoamine oxidase inhibitors) for depression.
- have **high blood pressure** due to a **tumour near your kidney** called 'phaeochromocytoma' or 'paraganglioma'
- have porphyria (a rare, inherited blood disorder)

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

Warnings and precautions:

Talk to your doctor or pharmacist before taking Methyldopa tablets if you have:

- a blood disorder called haemolytic anaemia
- liver problems
- jaundice (yellowing of the skin and eyes)
- fever
- any 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 medicines obtained without a prescription as some drugs may affect each other's action. This includes herbal medicines.

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

It is particularly important that you tell your doctor or pharmacist if you are taking any of the following before taking Methyldopa

- other medicines for high blood pressure (antihypertensives)
- 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
- cough and cold remedies that contain a decongestant
- medicines used as muscle relaxants : tizanidine and baclofen
- medicines used to treat parkinson's disease e.g entecapone
- steroids e.g prednisolone
- medicines to treat psychosis e.g. haloperidol
- medicines used to treat erectile dysfunction e.g alprostadil
- medicines to treat anxiety
- 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.

Tests you may have while taking Methyldopa

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 you are taking Methyldopa if you have a laboratory test where a urine or blood sample is taken. This is because Methyldopa may affect the results of some types of tests.

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

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.

Pregnancy, breast-feeding and fertility

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.

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

Methyldopa with alcohol

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

Driving and using machines

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

Important information about some of the ingredients of Methyldopa Tablets

This medicinal product contains:

- lactose - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- sunset yellow E110, which may cause allergic reactions.

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.

Taking this medicine

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

The breakline on Methyldopa 500mg film-coated tablets is not intended for breaking the tablets.

The recommended dose is:**Adults and children over 12 years:**

- The recommended 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 recommended 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 take too many tablets by mistake, contact your doctor immediately or seek medical attention.

If you forget to take Methyldopa Tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Methyldopa Tablets

Do not stop taking Methyldopa without talking to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause 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).

The following reactions have also been reported:

Blood:

- 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
- 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
- being unable to move part of your face (paralysis)
- having movements you cannot control
- 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 or 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:
 - a decrease in blood cell production
 - an increase in some white blood cells
 - abnormal levels of prolactin

Methyldopa 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, pharmacist or nurse. 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. 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 use the medicine after the expiry date which is stated on the side of the carton after 'Exp'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Blisters: Store in the original package.
- Container: Keep the container tightly closed.
- 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**

The active ingredient in your tablets is methyldopa.

- Each Methyldopa 250mg Tablet contains methyldopa equivalent to 250mg of anhydrous methyldopa.
- Each Methyldopa 500mg Tablet contains methyldopa equivalent to 500mg of anhydrous methyldopa.

The other ingredients are lactose monohydrate, povidone, sodium starch glycolate, magnesium stearate, hydroxypropyl methylcellulose, propylene glycol, polyethylene glycol, colours: titanium dioxide (E171), quinoline yellow aluminium lake (E104), iron oxide yellow (E172) and sunset yellow aluminium lake (E110).

What Methyldopa tablets look like and contents of the pack

- Methyldopa 250mg Tablets are yellow, circular, normal convex film-coated tablets.
- Methyldopa 500mg Tablets are yellow, circular, normal convex, film-coated tablets with breakline on one side.

Pack sizes:

- 250mg tablets: Containers of 56, 84, 100, 500 and 1000 tablets and blister pack of 56 tablets
- 500mg tablets: Containers of 56, 84, 100 and 500 and blister pack of 56 tablets.

Not all pack sizes may be marketed.

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