

Patient Information Leaflet

METHYLDOPA 250MG & 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).

In this leaflet:

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

1. What Methyldopa is and what it is used for

Methyldopa is a member of group of medicines called antihypertensive drugs or alpha adrenergic agonists. Methyldopa is converted to a natural chemical in the body which acts to lower blood pressure and is thought to do this by acting on the brain mechanism for controlling blood vessel size. This medicine is used to treat mild, moderate or severe high blood pressure (hypertension).

2. What you need to know before you take Methyldopa

Do not take Methyldopa Tablets if you:

- are sensitive or allergic to methyldopa or any of the ingredients of this tablet (listed in section-6)
- are suffering from depression
- have liver problems
- are being treated for high blood pressure due to a tumour of the adrenal gland
- are on treatment with monoamino oxidase inhibitors

Warnings and precautions

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

- are pregnant, planning to become pregnant or breast feeding
- have angina
- had a stroke
- have kidney problems
- have a condition called porphyria
- are allergic to tartrazine

If you are to undergo dialysis you should inform your doctor, as methyldopa is removed by dialysis.

If you are to undergo surgery, blood transfusion or laboratory tests you should inform your doctor of your treatment with methyldopa.

You may need to undergo liver function tests and blood tests during the first 6 to 12 weeks of treatment, during long-term treatment or if you develop an unexplained fever.

If you are not sure or confused consult your doctor or pharmacist.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking:

- other drugs that lower high blood pressure (eg: clonidine, enalapril, hydralazine, diltiazem, losartan, atenolol, nitrates etc)

- medicines called ‘tricyclic antidepressant’, used to treat depression and other mental disorders (eg: amitriptyline, isocarboxazid, lithium, chlorpromazine, thioridazine and haloperidol)
- decongestants, which are used to clear blocked nasal passages and sinuses (eg: ephedrine and phenylpropanolamine)
- muscle relaxants (eg: baclofen and tizanidine)
- aldesleukin, which is used to treat kidney cancer
- levodopa and amantadine, which are used to treat Parkinson’s disease (a condition causing tremors or shaking of the limbs in an uncontrolled fashion)
- corticosteroids used to treat inflammation
- moxislyte, which is used to treat Raynaud’s syndrome (a condition affecting the small blood vessels usually in the hands and feet)
- oestrogens (used as a combined oral contraceptive (‘the pill’) or hormone replacement therapy)
- salbutamol, which is used in asthma and bronchospasm
- anti-emetics, which are used to relieve vomiting, and nausea (eg: perphenazine)
- medicines containing iron, such as multivitamins with minerals
- sympathomimetics (such as adrenaline. Other adrenaline like medicines which are included in most cough /cold remedies)
- a group of medicines called “phenothiazines” such as chlorpromazine
- monoamines oxidase inhibitors used to treat depression

If you are not sure, talk to your doctor or pharmacist before taking these tablets.

Taking this medicine with food and drink

Avoid alcohol while taking these tablets as it may increase the sedative effects of methyldopa.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast feeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

As this medicine may make you drowsy, you should not drive or operate machinery until you know how the drug affects you.

Methyldopa tablet contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as it contains lactose.

3. How to take Methyldopa

Always take methyldopa exactly as your doctor has told you. The pharmacists label should tell how much to take and how often. 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 prescribes. Do not take more or less than your doctor has prescribed. If you’re not sure ask your doctor or pharmacist. You should swallow the tablet with a glass of water.

Dosage

Adults: The usual initial dose is 250mg, two or three times daily, for the first two days. If required, your doctor may adjust this dose, by 250mg per day or at intervals of at least two days.

The maximum daily dose is 3000mg.

Children: If methyldopa is prescribed for a child, make sure that the tablets are taken as stated on the label.

The dosage for children is worked out on the basis of the child’s weight in kilograms. The initial dose is usually 10mg per kg body weight daily, given in two

or four doses. The number of tablets may be increased or lowered at intervals if required, by your doctor. The maximum daily dose for children is 65mg per kg body weight or 3000mg, whichever is less.

Elderly: The initial dose should not exceed 250mg daily. If required, your doctor may adjust this dose. The maximum daily dose for elderly people is 2000mg.

If you take more tablets than you should

If you or anyone else has taken a large dose contact your nearest hospital casualty department or doctor immediately. Bring any remaining tablets with you to show the doctor.

If you forget to take a dose

Do not worry just take your tablets as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Methyldopa Tablets can cause side effects, although not everybody gets them.

Tell your doctor as soon as possible, if you notice any of the following serious side effects such as:

- chest pain, slow heart rate, or existing angina made worse
- 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

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)
- mental changes, including nightmares or depression

Nose and chest:

- nasal stuffiness

Stomach and gut:

- feeling sick, being sick, diarrhoea
- abdominal pain, feeling bloated
- constipation, excess wind
- 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

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

Keep all medicines out of the sight and reach of children

- Do not use the tablets after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep container tightly closed.
- Store in original container to protect from light.

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

Methyldopa tablets 250mg & 500mg:

- **The active substance is** methyldopa equivalent to either 250mg of anhydrous methyldopa or 500mg of anhydrous methyldopa.
- **The other ingredients are** lactose monohydrate, Povidone, sodium starch glycollate, magnesium stearate, hypromellose (E464), propylene glycol, polyethylene glycol and the colour titanium dioxide (E171), quinoline yellow aluminium lake (E104), iron oxide yellow (E172) and sunset yellow aluminium lake (E110).

See end of section 2 for further information on lactose.

What Methyldopa tablets looks like and contents of the pack

- **Methyldopa 250mg tablets** are yellow, circular, film coated tablets embossed PV on one face and, MD/250 on reverse.
- **Methyldopa 500mg tablets** are yellow, circular film coated tablets embossed PV on one face and MD/500 on the reverse.
- **Methyldopa 250mg tablets** are available in packs containing “7, 14, 28, 56, 84, 100, 500 and 1000 tablets”
- **Methyldopa 500mg tablets** are available in packs containing “7, 14, 28, 56, 84, 100, 500 and 1000 tablets”

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer:

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.

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To request a copy of this leaflet in large print or audio format or additional copies, please contact the licence holder at the address (or telephone, fax) above.

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