

PACKAGE LEAFLET: INFORMATION FOR THE USER
Methyldopa 250mg and 500mg Film-Coated Tablets
(Methyldopa)

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, please ask your doctor or pharmacist.
- This medicine has been prescribed only 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 this medicine 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 this medicine is and what it is used for

Methyldopa belongs to a group of medicines called antihypertensive agents, which lower blood pressure.

Methyldopa tablets are used to treat high blood pressure (hypertension).

2 What you need to know before you take Methyldopa

Do not take Methyldopa if:

- You are allergic (hypersensitive) to Methyldopa, other antihypertensive agents or any of the other ingredients of this medicine (see section 6 “Contents of the pack and other information”)
- You have previously taken Methyldopa and had liver problems
- You have liver disease, such as acute (short-lived) hepatitis or cirrhosis
- You suffer from depression
- You are taking monoamine oxidase inhibitors (MAOIs) for depression
- You have high blood pressure due to a tumour near the kidney (phaeochromocytoma)

Warnings and precautions

Talk to your doctor before taking Methyldopa:

- If you have had liver disease
- If you have kidney disease
- If you are to have kidney dialysis. Methyldopa is removed by dialysis, therefore your high blood pressure may return
- If you are known to have a genetic/inherited disorder of the red blood pigment haemoglobin (porphyria)
- If you have had a stroke or any other disorders of the blood vessels in your brain
- If you suffer from haemolytic anaemia (a reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness)
- If you are due to have a lab or blood test as Methyldopa may interfere with the results (see section 4 “Laboratory tests”)
- If you are due to have an anaesthetic as you may require reduced doses of anaesthetic when taking Methyldopa
- If your treatment with Methyldopa is likely to be long-term as you may develop a positive direct Coombs test. It is important that you talk to your doctor about your treatment with Methyldopa if you are due to have a blood transfusion

Other medicines and Methyldopa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

You must not take Methyldopa if you are taking the following:

- Monoamine oxidase inhibitors (MAOIs) for depression

You should tell your doctor if you are taking any of the following:

- Lithium for depression and mental illnesses
- Tricyclic antidepressants for depression e.g. amitriptyline, clomipramine
- Other antihypertensive medicines for high blood pressure e.g. propranolol, nifedipine, verapamil or diuretics 'water tablets'
- Sympathomimetics, used in emergency treatment for shock and anaphylaxis and also for coughs and colds e.g. ephedrine and salbutamol
- Phenothiazines for anxiety, feeling sick (nausea) or being sick (vomiting) or mental disorders e.g. trifluoperazine
- Iron supplements
- Alprostadil for erectile dysfunction
- NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) for the relief of pain e.g. ibuprofen
- Linezolid for some bacterial infections
- Antipsychotics used for mental illnesses such as schizophrenia e.g. amisulpride
- Medicines for anxiety or insomnia e.g. diazepam and temazepam
- Corticosteroids for inflammation or to suppress the immune system e.g. prednisolone and hydrocortisone
- Levodopa or entacapone for Parkinsonism
- Moxisylyte for Raynaud's syndrome
- Baclofen and tizanidine for relaxing muscles
- Nitrates for chest pain (angina) e.g. glycerol trinitrate "GTN" and isosorbide dinitrate/mononitrate
- Combined oral contraceptive ("the pill") or Hormone Replacement Therapy (HRT)
- Carbenoxolone for ulcers

Taking Methyldopa with alcohol

You are advised **not to drink** alcohol with this medicine. If alcohol and Methyldopa are taken together it may increase the effect of lowering blood pressure.

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 for advice before taking this medicine.

Pregnancy

If you are pregnant, the use of Methyldopa should be avoided as Methyldopa is passed into cord blood.

Breast-feeding

If you are breast-feeding, the use of Methyldopa should be avoided as Methyldopa is passed into breast milk.

Driving or using machines

Methyldopa may make you feel drowsy. This is usually short lived and more likely to occur when starting treatment or whenever the dose is increased. If affected do not drive or use machinery as it may be dangerous.

Methyldopa contains the colouring agent Sunset Yellow FCF (E110)

May cause allergic reactions.

3 How to take Methyldopa

Always take Methyldopa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- These tablets should be swallowed with a little water.

Adults

- The recommended dose is 250mg two or three times daily.
- Your doctor may gradually increase your dose, every 2 or more days, by an additional 250-500mg daily until satisfactory control of blood pressure is achieved. The usual effective dose is in the range of 500–2000mg a day.
- The maximum dosage is 3000mg daily.
- Patients with kidney problems may be given a lower dose.

Use in children

- The recommended dose is 10mg/kg of body weight daily in 2–4 divided (oral) doses. The daily dose is then increased or decreased as required.
- The maximum dosage is 65mg/kg or 3000mg daily, whichever is less.

Older people

- The initial dose should be as low as possible, usually about 125mg twice a day (maximum 250mg a day). The dose should be increased gradually as required.
- The maximum dosage is 2000mg daily.

If you take more Methyldopa than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose may include: excessive drowsiness, weakness, slower heartbeat, dizziness, light-headedness, constipation, bloated feeling, wind, diarrhoea, feeling sick or being sick.

If you forget to take Methyldopa

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Methyldopa

It is important that you keep taking Methyldopa for as long as your doctor has told you to.

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 can cause side effects, although not everyone gets them.

Seek medical advice immediately if you develop the following:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Severe blistering of the skin, mouth, eyes and genitals (toxic epidermal necrolysis)
- Liver disorders including inflammation of the liver (hepatitis) and yellowing of the skin or whites of the eyes (jaundice) and other recognisable signs e.g. abdominal pain, feeling or being sick (nausea/vomiting), dark coloured urine
- The recognisable signs (e.g. sudden fever, sore throat, mouth ulcers, any signs of infection) of:
 - Bone marrow depression (abnormal condition of the bone marrow in which it is unable to produce normal amounts of red blood cells, white blood cells, and platelets leaving the immune system in a weakened state and vulnerable to infection)
 - Thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising)
 - Other blood disorders (see “Other side effects”)

Most common side effect

- Drowsiness (usually short lived and may occur when starting treatment or the dose is increased)

Other side effects (frequency not known)

- Headache
- Tingling or numbness in the hands or feet (paraesthesia)
- Tremor, stiffness and shuffling (Parkinsonism)
- Paralysis or weakness of the facial muscles on one side (Bell’s palsy)
- Involuntary jerky movements
- Nightmares, confusion, mild depression, due to mental changes

- Dizziness, light-headedness or fainting (prolonged carotid sinus hypersensitivity), particularly on standing up quickly, due to a lowering of blood pressure (orthostatic hypotension)
- Slower heartbeat (bradycardia)
- Chest pain, fever, faster or irregular heartbeat, tiredness or shortness of breath, due to inflammation of the heart muscle or lining surrounding the heart (myocarditis, pericarditis)
- Worsening of existing chest pain (angina)
- Reduction in white blood cells, which may make infections more likely (leucopenia, granulocytopenia)
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough & rashes due to an increase in certain white blood cells (diagnosed through blood test) (eosinophilia)
- Loss of strength or weakness (asthenia)
- Swelling and weight gain, due to water retention
- Bloating stomach
- Constipation
- Wind
- Diarrhoea
- Abdominal pain or diarrhoea, due to inflammation of the colon (colitis)
- Mild dryness of the mouth
- Sore or 'black' tongue
- Severe pain in the abdomen and back, due to inflammation of the pancreas (pancreatitis)
- Rash (eczema or lichenoid eruption)
- Mild joint pain (arthralgia) and/or joint swelling and muscle pain (myalgia)
- Stuffy nose
- Tender or painful lump in the cheek or under the chin, due to inflammation of the salivary glands (sialadenitis)
- Swelling of breasts in both men and women
- Production of breast milk (lactation)
- Stopping of menstrual periods (amenorrhoea)
- Failure to ejaculate
- Reduced sex drive
- Weakness or breathlessness, due to a reduction in red blood cells (haemolytic anaemia)
- Abnormally high levels of prolactin in the blood (hyperprolactinaemia)
- Joint pain, skin rashes and fever (Lupus like syndrome)
- Inability to maintain an erection (impotence)
- Drug-related fever

Laboratory tests

Methyldopa may affect the results of certain laboratory tests, such as the following:

Coombs (see section 2 "Warnings and precautions"), antinuclear antibody, LE cells, rheumatoid factor, blood urea and liver function

Reporting 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 internet 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 this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton/label after EXP. The expiry date refers to the last day of that month.
- Store in a cool, dry place. Store in the original package in order to protect from the light.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Methyldopa contains:

- Each 250mg film-coated tablet contains 283mg of Methyldopa equivalent to 250mg anhydrous methyldopa
- Each 500mg film-coated tablet contains 565mg of Methyldopa equivalent to 500mg anhydrous methyldopa

The other ingredients are: microcrystalline cellulose, starch, povidone, magnesium stearate, sodium starch glycollate, methanol

Coating: methanol, methylene chloride, methocel (E15) premium, ethocel 10 CPS, diethyl phthalate and:

- Methyldopa 250mg contains opaspray K-1-8423 (yellow) containing; titanium dioxide (E171), quinoline yellow (E104), sunset yellow FCF (E110), indigo carmine (E132)
- Methyldopa 500mg contains opaspray K-1F-6035 (yellow) containing; titanium dioxide (E171), quinoline yellow (E104), sunset yellow FCF (E110), indigo carmine (E132) and opaspray K-1-17000 (white) containing titanium dioxide (E171)

What Methyldopa looks like and contents of the pack:

- Methyldopa 250mg are yellow, biconvex, film-coated tablets with an approximate diameter of 10.5mm, either plain or coded "MYD 250" on one side.
- Methyldopa 500mg are yellow, biconvex, film-coated tablets with an approximate diameter of 12.5mm, either plain or coded "MYD 500" on one side.

Methyldopa is available in:

Methyldopa tablets are available in packs of 50, 56, 100, 250, 500 or 1,000 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

PL 45816/0002 (250mg)

PL 45816/0003 (500mg)

Marketing Authorisation Holder:

Pharmapoint UK Ltd
30 Hatfeild Mead,
Morden,
Surrey, SM4 5PE,
United Kingdom

Manufacturer:

Central Pharma (Contract Packing) Limited
Caxton Road
Bedford, MK41 0XZ
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