

## Package leaflet: Information for the patient

# Methyldopa 125 mg 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, ask your doctor or your 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

This medicine contains Methyldopa which belongs to a group of medicines called 'antihypertensives'.

Methyldopa is changed inside your body to a natural substance that lowers blood pressure. Your doctor has prescribed Methyldopa to treat high blood pressure (hypertension).

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

#### Do not take Methyldopa if you have:

- ever had a bad reaction, such as an allergy to methyldopa, or to any of the other ingredients (listed in section 6)
- ever had liver disease
- ever had depression
- high blood pressure due to a tumour near your kidney called 'phaeochromocytoma' or 'paraganglioma'
- been taking a type of medicine called a 'monoamine oxidase inhibitor' (MAO inhibitor)
- 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 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

#### 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.

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

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

#### Other medicines and Methyldopa:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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
- 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.

#### 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 with alcohol

You are advised not to drink alcohol with this medicine. Discuss this with your doctor if you have any questions.

#### 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 before taking this medicine.

#### 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.

#### This medicine 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.

### 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 recommended doses of Methyldopa are:

#### Adults

- 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.

#### 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 recommended 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.

XXXXXX

- 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 than you should**

If you take too many tablets by mistake, contact your doctor immediately or seek medical attention. If an overdose has been taken, there may be signs such as excessive drowsiness, weakness, slow heart rate, dizziness, light-headedness, painful infrequent bowel movements, bloated feeling, wind, diarrhoea, feeling or being sick.

#### **If you forget to take Methyldopa**

- If you forget to take a dose, just carry on with the next dose as normal.
- Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Methyldopa**

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.

**Tell your doctor immediately, if you notice 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
- 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
- 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
- breast development in men

#### **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](http://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 this medicine after the expiry date which is stated on the carton after 'EXP'. This expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package in order 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**

- The active substance is methyldopa.
- The tablets also contain Citric Acid, Lactose, Starch, Talc, Magnesium Stearate, Stearic Acid, Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol, Titanium Dioxide (E171) and Yellow Iron Oxide (E172).

#### **What Methyldopa Tablets look like and contents of the pack**

- Methyldopa Tablets are Yellow, circular, bi-convex film-coated tablets embossed with '125' on one side and 'BL' on the reverse.
- Methyldopa 125 mg Tablets are packed in blister pack containing 56 tablets.

#### **Marketing Authorisation Holder and Manufacturer**

Name and address:

Bristol Laboratories Limited  
Unit-3, Canalside, Northbridge Road,  
Berkhamsted, HP4 1EG, United Kingdom  
Telephone: 0044(0) 1442200922  
Fax: 0044(0) 1442873717  
Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

#### **Methyldopa 125 mg Tablets; PL 17907/0461**

#### **This leaflet was last revised in September 2016**

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