

PACKAGE LEAFLET: INFORMATION FOR THE USER

METHYLDOPA

250 mg Film-coated Tablets

METHYLDOPA

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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2. Before you take METHYLDOPA
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1. WHAT METHYLDOPA IS AND WHAT IS IT USED FOR

Methyldopa contains a medicine called methyldopa. This 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. BEFORE YOU TAKE METHYLDOPA

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
- ever had liver disease
- ever had depression
- high blood pressure due to a tumour near your kidney called 'phaeochromocytoma'.
- been taking a type of medicine called a 'monoamine oxidase inhibitor' (MAO inhibitor)

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

Take special care with Methyldopa

Check with your doctor before taking this medicine if you have:

- or anyone in your family has an illness called 'hepatic porphyria'
- kidney problems
- had a stroke

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.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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
- 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 apply to you, talk to your doctor or pharmacist before taking Methyldopa.

Pregnancy and breast-feeding

You should check with your doctor before taking Methyldopa if you are or think you may be pregnant, if you are planning to become pregnant or if you are breast-feeding.

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.

3. HOW TO TAKE METHYLDOPA

Always take Methyldopa exactly as your doctor 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 usual doses of Methyldopa are:

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 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

- 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, Methyldopa 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)

Nose and chest:

- nasal stuffiness

Stomach and gut:

- feeling sick
- being sick
- abdominal pain
- feeling bloated
- constipation
- excess wind
- diarrhea
- 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

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. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE METHYLDOPA

Keep out of the reach and sight of children.

Do not use the medicine past 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.

Store in the original package in order to protect from light.

If you have any medicine left over when your doctor tells you to stop using it, return it to the pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.