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PACKAGE LEAFLET: INFORMATION FOR THE USER
Methyldopa Tablets B.P. 250 mg & 500 mg

(referred to as Methyldopa Tablets in the remainder of the leaflet)

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, pharmacist or nurse.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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
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1. What Methyldopa Tablets are and what they are used for

The name of this medicine is Methyldopa Tablets.
Methyldopa, the active ingredient in these tablets, belongs to a group of medicines called antihypertensives. These medicines work by lowering blood pressure. Methyldopa Tablets may be used for the treatment of severe hypertension (high blood pressure).

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

Do not take Methyldopa Tablets and tell your doctor if you:
- are allergic to methyldopa or any of the other ingredients in the tablets (see section 6)
- have a history of depression
- have been diagnosed as having a liver disorder such as acute hepatitis, active cirrhosis
- are taking MAOIs (monoamine oxidase inhibitors) for depression.
- porphyria (a rare, inherited blood disorder)
- have high blood pressure due to a tumour near your kidney called 'phaeochromocytoma' or 'paraganglioma'

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

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you have:
- a blood disorder called haemolytic anaemia
- liver problems
- jaundice (yellowing of the skin and eyes)
- fever
- ever had a stroke
- 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 Tablets
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 tablets. Tell your doctor you are taking Methyldopa tablets if you have a laboratory test where a urine or blood sample is taken. This is because Methyldopa tablets may affect the results of some types of tests.
Rarely, in patients taking Methyldopa tablets 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 tablets.

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 affect each other's action. This include herbal medicine

Do not take Methyldopa tablets 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 tablets
- antihypertensive medicines used to treat high blood pressure (e.g. verapamil)
- medicines to treat Parkinson's disease (e.g. levodopa)
- lithium - used to treat depression and mental illness
- medicines to treat mental illness and sometimes feeling and being sick (e.g. phenothiazines, such as chlorpromazine and butyrophenones such as haloperidol)
- medicines called 'tricyclic antidepressants' used to treat depression
- sympathomimetics (medicines used mainly for coughs and colds that contain a decongestant (e.g. pseudoephedrine)
- iron and supplements containing iron, such as multivitamins with minerals
- diuretic medicines used to increase urine output.

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

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 and breast-feeding
You must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. Your doctor will then decide whether you should take this medicine.
Methyldopa passes into breast milk, therefore, if you are breast-feeding, this medicine should be avoided. Your doctor will be able to discuss this with you to determine whether the anticipated benefits are worth the possible risks.

Driving and using machines
Methyldopa Tablets may make you feel drowsy or light-headed. If this occurs, you should avoid driving or using machinery.

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

Important information about some of the ingredients of Methyldopa Tablets:
These tablets contain 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 Methyldopa Tablets as your doctor tells you to. Check with your doctor or pharmacist if you are not sure.They will prescribe a suitable dose for you. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and body weight. Your doctor will find the lowest dose to control your symptoms.

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 tablets for as long as your doctor has prescribed. Do not take more or less than your doctor has prescribed.
The usual doses of Methyldopa tablets are:

Adults and children over 12 years:
- 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.

Children under 12 years:
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.

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.

If you take more Methyldopa Tablets than you should:
If you take too much medicine or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away. Symptoms of overdose may include lowered blood pressure, drowsiness, weakness, reduced heart rate, dizziness, light-headedness (i.e. feeling faint), gastrointestinal disturbances e.g. constipation, bloating, flatulence, diarrhoea, nausea and vomiting.

If you forget to take Methyldopa Tablets:
If you forget to take one dose, you should never make up for the missing dose by doubling the dose next time. Instead you should simply continue with the next dose when it is due.

If you stop taking Methyldopa Tablets:
Do not stop taking Methyldopa Tablets 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 Tablets can cause side effects, although not everybody gets them. If any of the following happens, stop taking Methyldopa Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:
- 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.
This is a very serious side effect. You may need urgent medical attention or hospitalisation.
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, 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:
- your medicine may alter the numbers and types of your blood cells and cause a rise in urea in the blood.
- abnormal blood test causing symptoms such as pale skin, tiredness, fever and sore throat.
- bruising and prolonged bleeding after injury
- reduction in red blood cells (anaemia) - this can make your skin pale and make you weak or breathless

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)
- Parkinsonism - with symptoms such as tremor, a decrease in body movements with an inability to move your muscles

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
- 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 Tablets.

Results could show:
- a decrease in blood cell production
- an increase in some white blood cells
- abnormal levels of prolactin

Methyldopa Tablets may also interfere with the interpretation of certain blood and urine tests.

The frequency of all the possible side effects listed above is classed as 'not known', which means that it cannot be estimated from the available data.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Methyldopa Tablets

Do not store above 25ºC. Store in the original package in order to protect from light.
Keep this medicine out of the sight and reach of children.
This medicine must not be used after the expiry date on the pack. Return any left over medicine to your pharmacist. Only keep it if your doctor tells you to. 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.

6. Contents of the pack and other information

What Methyldopa Tablets contain:
The active substance is methyldopa. Each film-coated tablet contains either 250 mg or 500 mg of the active substance.
The tablets also contain citric acid, lactose monohydrate, maize starch, talc, magnesium stearate, stearic acid, hypromellose, macrogol 400, titanium dioxide (E171), yellow iron oxide (E172) and silica colloidal anhydrous (500mg only).

What Methyldopa Tablets looks like and contents of the pack
Methyldopa Tablets B.P. 250 mg are round yellow film-coated biconvex tablets.
Methyldopa Tablets B.P. 500 mg are round yellow film-coated biconvex tablets, each having 'M500' debossed on one side.
Methyldopa Tablets BP 250 mg and 500 mg are packed in blister strips in cartons containing 28 or 56 tablets.
Note: not all strengths and / or pack sizes may be available in all markets.

Marketing Authorization Holder
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Other formats
To request a copy of this leaflet in Braille, large print or audio please contact the licence holder at the above address.

PL 43461/0092 Methyldopa Tablets B.P. 250 mg
PL 43461/0093 Methyldopa Tablets B.P. 500 mg

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