Artwerk
creative designs
Artwork at upshot
e-mail : artwerkcd@gmail.com
prasad.pdp@gmail.com
Ph : +91-9845156610

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Ennogen

PACKAGE LEAFLET: INFORMATION FOR THE USER

Methyldopa 125mg, 250mg and 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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

Methyldopa Tablets contain the active ingredient methyldopa.
Methyldopa belongs to a group of medicines called 'anti-hypertensive' agents.
These tablets are used to treat high blood pressure (hypertension).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METHYLDOPA TABLETS

Do not take Methyldopa Tablets if:
- You are allergic to methyldopa or any of the other ingredients of this medicine (listed in section 6)
- You have ever had liver disease
- You have pheochromocytoma or paraganglioma (a rare tumour of the adrenal gland which causes high blood pressure)
- You suffer from depression
- You are taking monoamine oxidase inhibitors (MAOI) – a type of antidepressant
- You have porphyria (a rare inherited blood disorder).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Methyldopa Tablets if you have:
- Liver problems
- A blood disorder called haemolytic anaemia
- 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 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 this medicine.

Tell your doctor you are taking this medicine 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 this medicine 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.

Other medicines and Methyldopa Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Tablets if you are taking a type of medicine called a 'monoamine oxidase inhibitor' (MAOI) 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:
- 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 used when feeling sick or being sick
- Medicines called 'tricyclic antidepressants' – used to treat depression
- Iron and supplements containing iron, such as multivitamins with minerals.

Surgery
If you have to have surgery, including dental, that requires an anaesthetic, you must tell the dentist or hospital that you are taking Methyldopa Tablets.

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.

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 for advice before taking this medicine.

Driving and using machines
Methyldopa can make you feel sleepy. You should not drive, operate machinery or carry out other activities requiring full alertness whilst taking this medicine if you experience this effect.

Methyldopa Tablets contain soy lecithin (E322)
This medicine contains soy lecithin (E322), which may contain soya oil. If you are allergic to peanut or soya, do not take this medicine

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. HOW TO TAKE METHYLDOPA TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed with water.

Adults
Usual dosage:
The starting dose is 250mg twice a day for 2 days. This dose may be increased by your doctor by 250mg-500mg daily, at intervals of at least 2 days.
This increase may continue until satisfactory control of your blood pressure is achieved. Once control has been achieved, the daily dose will be in the region of 500mg-2000mg. You should not take more than 3000mg in a day.

Elderly
The starting dose may be lower. Your doctor will tell you exactly the dose to take and how often to take it.

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 10mg for each kg of body weight each day. This dose should be taken in two to four divided doses during the day.

The doctor may change the dose depending on how the child responds.

A child will not usually take more than 65mg per kg of body weight or 3000mg a day, whichever is less.

Patients with kidney problems
If you have problems with your kidneys, your starting dose may be lower than the adult dose above. Your doctor will tell you exactly the dose to take and how often to take it.

If you are already taking other medicines for high blood pressure (diuretics):
Your starting dose may be lower. You doctor will tell you exactly the dose to take and how often to take it.

The medicine you are currently taking will be gradually withdrawn and the dose of Methyldopa Tablets will be gradually increased.

This increase in dose of Methyldopa Tablets will be adjusted upwards by 250mg to 500mg at 2 to 7 day intervals to maintain control of your blood pressure.

If you take more Methyldopa Tablets than you should
If you take an unintentional extra dose, this should not be a problem. If you (or someone else) swallow a lot of tablets altogether, or if you think a child has swallowed one of the tablets, contact your nearest accident and emergency department or doctor immediately.

Symptoms of overdose include excessive drowsiness, weakness, slow heart rate, low blood pressure, dizziness, light-headedness, painful infrequent bowel movements, feeling bloated, wind, diarrhoea, feeling sick or being sick.

If you forget to take Methyldopa Tablets
If you forget to take a dose, take the missed dose as soon as you remember. If your next dose is due within 5 hours, skip the missed dose and take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Methyldopa Tablets
Do not stop taking these Tablets without talking to your doctor. The dose needs to be gradually reduced. If you stop taking these tablets you will experience a rise in blood pressure and your original symptoms will return.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor IMMEDIATELY if you have 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, fever or painful joints
- 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. The frequency of these are not known (frequency cannot be estimated from the available data).

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 (nausea)
- Being sick (vomiting)
- 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:
- Fever
- Water retention causing swelling and weight gain.

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 prolactin levels
- A positive result for antinuclear antibodies, LE cells and rheumatoid factor.

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 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

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 label. The expiry date refers to the last day of that month.
Methyldopa 125mg Tablets: Store in a cool dry place and protect from light.
Methyldopa 250mg and 500mg Tablets: Store below 25°C. protect from light.

Do not use this medicine if you notice visible signs of deterioration.

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.

Methyldopa 125mg Tablets contain 125mg of Methyldopa in each tablet.
Methyldopa 250mg Tablets contain 250mg of Methyldopa in each tablet.
Methyldopa 500mg Tablets contain 500mg of Methyldopa in each tablet.

The other ingredients are:
Sodium calcium edetate, citric acid, sodium starch glycolate, microcrystalline cellulose, ethyl cellulose, polyvinyl alcohol (E1203), magnesium stearate, colloidal anhydrous silica, purified talc (E553b), iron oxide yellow (E172), titanium dioxide (E171), soy lecithin (E322) and xanthan gum (E415).

What Methyldopa Tablets look like and contents of the pack
Methyldopa 125mg Tablets are yellow coloured, round, biconvex, film coated tablets plain on both sides with an approximate diameter of 8.1mm.

Methyldopa 250mg Tablets are yellow coloured, round, biconvex, film coated tablets plain on both sides with an approximate diameter of 11.6mm.

Methyldopa 500mg Tablets are yellow coloured, capsule shaped, biconvex, film coated tablets, plain on both sides with an approximate dimension of 19.10mm X 8.60mm.

Methyldopa Tablets are available in a pack size of 56 tablets.

Marketing Authorisation Holder
Ennogen IP Ltd
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK

Manufacturer
Ennogen Pharma Limited
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK.

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