PACKAGE LEAFLET: Information for the patient

METIL DOPA

Tablets – 250 mg

(Methyldopa)

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

In this leaflet:

1. WHAT METIL DOPA IS AND WHAT IT IS USED FOR

The mechanism of action of methyldopa has yet to be conclusively demonstrated, but probably it is due to the metabolism of this drug to alpha-methylnorepinephrine, which lowers arterial pressure by stimulation of central inhibitory alpha-adrenergic receptors. It gives false neurotransmission, and reduces plasma renin activity.

Metil dopa 250 mg tablets are indicated in the treatment of hypertension.

2. BEFORE YOU TAKE METIL DOPA

Do not take Metil dopa if you have:

- known hypersensitivity to methyldopa or to any of the excipients of the tablet;
- active liver diseases or history of such diseases;
- ever had depression;
- are taking monoamine oxidase inhibitors (MAOIs);
- phaeochromocytoma;
- porphyria.

Take special care with Metil dopa

During treatment with methyldopa, in 20% of patients, positive Coombs test may occur. In these cases, the doctor should determine whether hemolytic anemia exists or this test interferes with Metil dopa.

The initial dose of methyldopa should be reduced in patients with renal impairment.

Tell your doctor if you have heart problems, jaundice (yellowing of the skin and eyes), fever or any abnormal movements (involuntary).

During treatment, patients should be advised to perform blood count and liver function tests.

Caution is required in patients that have damaged blood vessels in brain.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Metil dopa.

Please, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not forget to inform your doctor about the treatment with Metil dopa if you are given another medicine during treatment.

It is particularly important to inform your doctor that you are taking:

- other antihypertensive medicines (enhanced hypotensive effect);
- antipsychotics (enhanced hypotensive effect and increased risk for extrapyramidal effects);
- anxiolytics and hypnotics (enhanced hypotensive effect);
- mono-amine oxidase inhibitors (MAOIs) (alter the effect of methyldopa on blood pressure);
- tricyclic antidepressants (alter the effect of methyldopa on blood pressure);

- alprostadil (enhanced hypotensive effect);
- moxisylyte (enhanced hypotensive effect);
- baclofen, tizanidine (enhanced hypotensive effect);
- nitrates (enhanced hypotensive effect);
- beta-blocking agents (enhanced hypotensive effect);
- corticosteroids (antagonise the hypotensive effect of methyldopa);
- levodopa or entacapone (enhanced hypotensive effect);
- lithium carbonate (risk for neurotoxicity);
- $ß_2$ -sympathomimetics (risk of hypotension);
- oral iron sulfate (ferrous) (antagonises the hypotensive effect of methyldopa);
- nonsteroidal antiinflamatory drugs (antagonise the hypotensive effect of methyldopa);
- estrogens (antagonise the hypotensive effect of methyldopa).

Taking Metil dopa with food and drinks

Concomitant alcohol consumption with this medicine, enhances the hypotensive effect.

Pregnancy

Methyldopa is used commonly for the control of hypertension during pregnancy. There are little evidences for adverse effects on fetal development. Anyway, this drug crosses placenta.

Breastfeeding

Methyldopa is distributed in breast milk in small quantities, which are considered not harmful for the child.

Driving and using machines

Methyldopa may cause sedation and impair the ability of the patient to drive or use machines.

Important information about some of the excipients of Metil dopa

Metil dopa contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE METIL DOPA

Always take Metil dopa tablets only as your doctor has told you. If you feel that the effects of Metil dopa are too strong or too weak, talk to your doctor or pharmacist.

The dosage is as follows:

Initially, 250 mg 2 – 3 times daily, for 2 days are used. Then, the dose is increased gradually in intervals of not less than 2 days, until the appropriate clinical response is achieved. The maximum dose is 3 g. To minimize the sedative effect, the dose increase is started in the evening. Lower doses may be used by combining methyldopa with thiazide diuretics (e.g., 500 mg methyldopa + 50 mg hydrochlorothiazide, once daily).

If you take more Metil dopa than you should

If you take more Metil dopa than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures to be taken.

If you forget to take Metil Dopa

If you forget to take one dose, take the next dose in its usual time.

Do not take a double dose to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Metil dopa can cause side effects, although not everybody gets them.

Sometimes they are serious, sometimes not.

Do not panic by this list of possible side effects!

You may not get any of them.

Very common side effects are:

- drowsiness, mainly at the beginning of treatment and in case of a dose increase; dizziness and light-headedness may be associated with orthostatic hypotension, nausea, headache, weakness and fatigue;

- mental and neurological effects of methyldopa include: concentration and memory impairment, mild psychosis, depression, sleep disorders and nightmares, paresthesia, facial paralysis, choreathetoid involuntary movement and parkinsonism;
- methyldopa often is associated with fluid retention and oedema, a condition which responds to diuretics and rarely may advance to cardiac failure; angina pectoris may be exacerbated; bradycardia, syncope, and prolonged carotid sinus hypersensitivity have been reported;
- gastrointestinal disorders incuding: nausea and vomiting, diarrhea, constipation and rarely pancreatitis and colitis; dry mouth is a usual condition, but also darkening of the tongue and salivary glands inflammation have occurred;
- in 10-20 % of patients with prolonged treatment, positive Coombs test may occur, but only a few of them develop hemolytic anemia. Thrombocytopenia and leucopenia, obvious granulocytopenia have occurred, which require immediate discontinuance of the drug.

Other hypersensitivity effects include: myocarditis, antinuclear antibodies may develop and a lupus-like syndrome, fever, eosinophilia, liver function disturbances, rash, granulomatous eruption and lichenoids, toxic epidermal necrolysis, flu - like syndrome (fever, myalgia and mild arthralgia), nocturia, uremia, nasal congestion and retroperitoneal fibrosis. Hyperprolactinaemia may occur, with breast enlargement or gynaecomastia, galactorrhoea, and amenorrhoea.
In the first 2-3 months of therapy hepatitis may develop, but generally it is reversible on drug discontinuance. Anyway, fatal hepatic necrosis have occurred.
In some cases, Metil dopa may cause darkening of urine when it is exposed in the air, due to the destruction of the drug or its metabolites.
There have been occasional reports of decreased libido and impotence.
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 METIL DOPA

Keep away from children!
Do not use Metil dopa after the expiry date which is stated on the package.
Do not store above 25°C!
Keep in the original package to protect it from light.

6. FURTHER INFORMATION

What Metil dopa 250 mg tablets contain

The active substance is methyldopa.

Each tablet contains 250 mg methyldopa.

The excipients microcrystalline cellulose, lactose, magnesium stearate, colloidal anhydrous silica and talc.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "“Skënder Vila",”

Tirana, Albania.

Tel.: +355 4 23 89 602

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