

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you starts giving 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, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist

In this leaflet:

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1. What are and What they are used for

contains the active substance 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 to treat high blood pressure (hypertension).

2. What you need to know before you take Tablets

Do not take M DOPAKANT-250 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 M DOPAKANT-250 if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before taking M DOPAKANT-250.

Take special care with M DOPAKANT-250

Talk to your doctor or pharmacist before taking M DOPAKANT-250 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 M DOPAKANT-250

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 M DOPAKANT-250.

Tell your doctor you are taking

M DOPAKANT-250 if you have a laboratory test where a urine or blood sample is taken. This is because M DOPAKANT-250 may affect the results of some types of tests. Rarely, in patients taking M DOPAKANT-250 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 M DOPAKANT-250.

Other medicines and M DOPAKANT-250

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 M DOPAKANT-250 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 M DOPAKANT-250

- 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 M DOPAKANT-250.

Surgery

If you have to have surgery, including dental, that requires an anaesthetic, you must inform the dentist or hospital that you are taking M DOPAKANT-250 tablets.

M DOPAKANT-250 with alcohol

You are advised not to drink alcohol while taking M DOPAKANT-250 tablets. Discuss this with your doctor if you have any questions.

Pregnancy and breast-feeding

You should check with your doctor before taking M DOPAKANT-250 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 M DOPAKANT-250. If this happens do not drive or use any tools or machines.

3. How to take M DOPAKANT-250

Always take M DOPAKANT-250 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 M

DOPAKANT-250 for as long as your doctor has prescribed. Do not take more or less than your doctor has prescribed. The usual doses of M DOPAKANT-250 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 M DOPAKANT-250 than you should

If you take too many tablets by mistake, contact your doctor immediately or seek medical attention.

If you forget to take M DOPAKANT-250

- 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 M DOPAKANT-250

Do not stop taking M DOPAKANT-250 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, M DOPAKANT-250 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 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
- 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 M DOPAKANT-250.

Results could show:

- a decrease in blood cell production
- an increase in some white blood cells
- abnormal levels of prolactin M DOPAKANT-250 may also interfere with the interpretation of certain blood and urine tests.

5. How to store M DOPAKANT-250 Tablets

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 30°C.

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

Bottles: Keep the container tightly closed in order to protect from light.

Medicines should not be disposed of via waste water 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 M DOPAKANT-250 contain:

Active substances

The active ingredient in Methyldopa Tablets is Methyldopa BP

M DOPAKANT-250 containing methyldopa equivalent to 250 mg anhydrous methyldopa.

Other ingredients

Citric Acid Monohydrate BP, Disodium Edetate BP, Ethyl Cellulose 22CPS BP, Guar gum BP, Colloidal Silicon Dioxide BP, Magnesium Stearate BP, Isopropyl Alcohol BP, Titanium dioxide(Wincoat-WT-1003) HIS, Methylene chloride BP

What looks like and contents of the pack:

White to yellowish white coloured, circular, film coated, biconvex tablets plain on both side.

M DOPAKANT-250 are packed in ALU-PVC/PVDC blister pack-
10 x 10 tablets blisters in a carton along with insert.
1000 tablets in a HDPE jar with insert

Manufactured by:



1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.