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PHARMACODE
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Roma Pharmaceuticals

Package leaflet: Information for the patient
Minoxidil 2.5 mg Tablets
Minoxidil 5 mg Tablets
Minoxidil 10 mg 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 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. See section 4.

The name of your product is Minoxidil 2.5 mg, 5 mg or 10 mg Tablets, but it will be referred to as Minoxidil Tablets throughout this leaflet.

What is in this leaflet

1. What Minoxidil Tablets are and what they are used for
2. What you need to know before you take Minoxidil Tablets
3. How to take Minoxidil Tablets
4. Possible side effects
5. How to store Minoxidil Tablets
6. Contents of the pack and other information

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

This medicine contains minoxidil, which is one of a group of medicines called 'vasodilators'. It can be used to treat very high blood pressure (hypertension) and works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

You must talk to your doctor or pharmacist if you do not feel better or if you feel worse.

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

Do not take Minoxidil Tablets
- If you are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6).
- If your high blood pressure is caused by hormones from a tumour (phaeochromocytoma), usually near the kidneys.

Warnings and Precautions
Talk to your doctor or pharmacist before using Minoxidil Tablets:
- If you are pregnant or trying to become pregnant.
- If you have heart failure (you may feel breathless, wheezy or tired and your ankles may swell up).
- If you have ever had a heart attack.

Minoxidil Tablets encourage salt and water to remain in your body. Too much salt and water in the body can make you feel breathless, wheezy, sick and tired, and can stop Minoxidil Tablets working properly. Minoxidil Tablets also make your heartbeat faster.

To avoid these problems, your doctor will prescribe two other medicines for you to take with Minoxidil Tablets. One will be a water tablet (diuretic) to help your body get rid of excess water, and the other a beta-blocker or similar medicine to stop your heart beating too fast or angina pain in the chest.

If your doctor gives you a low salt diet, follow it carefully. You should weigh yourself daily and keep an accurate record of your weight while you are taking this medicine. Tell your doctor if you put on more than 1 to 1.5kg. The cause could be extra fluid in your body. Tell your doctor if you think you have gained weight – even though it may not be due to the medicine. Your doctor will want to monitor fluid and salt (electrolyte) levels in your body.

You may recognise increased hair growth (hypertrichosis) after starting treatment, this usually emerges in the face but may subside with continued treatment. This side effect is reversible upon stopping treatment but may take one to six months.

Your doctor will want to make regular checks on your blood pressure and general health. You should also have occasional checks on your heart.

If you have an ECG test (to check the electrical activity of your heart) or any blood tests, remind your doctor that you are taking Minoxidil Tablets, as it can change the results.

Your doctor may monitor your blood for the very rare possibility of decreased white blood cells and platelets cells.

In some patients, inflammation of membrane around heart, fluid accumulation under the membrane around heart (cardiac tamponade) can occur. Your doctor should monitor these carefully and may try to drain the fluid or may consider stopping treatment with Minoxidil Tablets.

Patients with kidney failure and undergoing haemodialysis may need smaller doses of Minoxidil Tablets, which should be used with special care in these patients to maintain electrolyte balance in the body.

Other medicines and Minoxidil 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.

It is particularly important you tell your doctor about any other medicine you are taking to reduce your high blood pressure. These medicines may interact with Minoxidil Tablets by causing blood pressure to drop too low. In particular, tell your doctor if you are taking guanethidine or betanidine so you can be monitored whilst on treatment with Minoxidil Tablets or your doctor may consider stopping these therapies before starting treatment with Minoxidil Tablets.

Your doctor will tell you when and how to stop taking this medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have baby, ask your doctor or pharmacist for advice before taking this medicine. Minoxidil passes into breast milk and is not recommended if you are breast-feeding unless your doctor thinks it is necessary.

There are no fertility data from the use of minoxidil in humans.

Driving and using machines
Minoxidil Tablets may make you feel faint or dizzy, particularly when you first start treatment or your dose is increased. If affected do not drive or operate machines.

Minoxidil 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 Minoxidil Tablets

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

Swallow Minoxidil Tablets whole with water.

The score line on the 2.5 mg tablets is not intended for breaking the tablet.

The 5 mg and 10 mg tablets can be divided into equal doses.

If you need to take half a tablet you should break it in half along the scored line on the tablet. Do not keep the remaining half tablet.

Adults and children over the age of 12
Your doctor might change your daily dose gradually to get the best results.

There should be at least three days between each change of dose. Don't wait until your tablets are finished before seeing your doctor.

The usual starting dose of Minoxidil Tablets for adults and children aged over 12 years is 5 mg each day. The dose can be increased to 20 mg and then 40 mg as single or divided doses if required for optimum blood pressure control. It is unusual to need more than 50 mg a day in adults and children aged over 12 years. In very rare instances your doctor can decide to use up to a maximum of 100 mg.

Elderly
For adults over 65, the usual starting dose is 2.5 mg each day.

Use in children 12 years and under
For children of 12 and under, the dose depends on their weight but they should not be given more than 1 mg per kilogram of body weight each day. The starting dose is normally 0.2 mg each day for each kilogram of their weight.

During treatment with minoxidil the child should be under specialist supervision. The daily dose of minoxidil will be determined by the specialist and it may be adjusted according to the child's needs. During treatment the child will be additionally treated with other medicines as decided by the specialist to prevent rapid heartbeat and accumulation of fluid in the body. You should contact the doctor if the child has any of the following: a very rapid heartbeat, rapid breathing, swelling of the legs, rapid weight gain, and reduced urine. While on treatment with minoxidil the child will need to be regularly seen by the doctor.

Patients on dialysis
If you are on dialysis you may need a lower dose, even though dialysis can remove minoxidil from your blood. Do not take your tablets in the two hours before your dialysis session. Take them after the dialysis, or more than two hours before.

Rapid reduction of blood pressure
Minoxidil Tablets may also be given to you in hospital to reduce your blood pressure very quickly. It would be given by a doctor or nurse under strictly monitored conditions at increasing doses of 5 mg every six hours until your blood pressure is normal.

If you take more Minoxidil Tablets than you should
Taking too many tablets may make you unwell. If you take too many tablets, tell your doctor straight away. If you feel faint or dizzy, or your skin gets unusually cold and pale, you may need to go to hospital.

If you forget to take Minoxidil Tablets
Do not worry. If you forget to take a tablet, miss out the forgotten dose completely and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Minoxidil Tablets
Do not stop taking your medicine or alter the dose you are currently taking without seeing your doctor first. Minoxidil Tablets helps to control your blood pressure.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following events have been reported in patients with high blood pressure being treated with Minoxidil Tablets:

Contact your doctor **immediately** if any of the following occur
- You may feel faint or dizzy, especially when you stand up.
- Your body could hold on to more water than normal: you may notice that your ankles get puffy, or your rings get tight, or you put on weight.
- You may find that you get more wheezy, breathless and tired, especially if you already have a weak heart.
- You may notice angina (usually pains in your chest) for the first time, or if you have angina already it could get worse.

Other side effects Minoxidil Tablets may cause are:
Very common: may affect more than 1 in 10 people
Increased heart rate, inflammation of the lining that surrounds the heart, abnormal electrocardiogram (ECG), increased hair growth, hair colour changes.

Common: may affect up to 1 in 10 people
Accumulation of fluid around the heart, compression of the heart due to a build up of fluid, fluid retention, gastrointestinal disorder.

Uncommon: may affect up to 1 in 100 people
Accumulation of fluid between the layers of tissue that line the lungs and chest cavity, breast tenderness.

Rare: may affect up to 1 in 1,000 people
Decrease in white blood cells, reduction in blood platelets, which increases risk of bleeding or bruising, serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome), inflammation and blistering of the skin, rash.

Not known: frequency cannot be estimated from the available data
Chest pains (angina), swelling of the ankles, feet or fingers associated with or independent of weight gain, reduced kidney function resulting in increased creatinine and urea levels in your blood, extensive peeling and detachment of the skin on much of the body surface (Toxic Epidermal Necrolysis).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Minoxidil 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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Minoxidil Tablets contains
- The active substance is minoxidil. Each tablet contains either 2.5 mg, 5 mg or 10 mg minoxidil. The other ingredients are lactose monohydrate, cellulose microcrystalline (E460), maize starch, silica colloidal anhydrous, magnesium stearate (E572).

What Minoxidil Tablets looks like and contents of the pack

Minoxidil 2.5 mg Tablets are round, white to off white tablets, approximately 5.5mm in diameter, with score line on one side and "2.5" debossed on the other side.

Minoxidil 5 mg Tablets are oval, white to off white tablets, approximately 5.3mm in width by 10.5mm in length, with score line on one side and "5" debossed on the other side.

Minoxidil 10 mg Tablets are round, white to off white tablets, approximately 9mm in diameter, with score line on one side and "10" debossed on the other side.

Your tablets are supplied in blister strips of 10 tablets in cartons containing 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Roma Pharmaceuticals Ltd
Gibraltar House,
Crown Square,
Centrum 100,
Burton-upon-Trent,
DE14 2WE, United Kingdom

Manufacturer
Galenica Pharmaceutical Industry S.A.
4-6, Asklipiou Str.
14568 Kryoneri, Attiki, Greece

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