

Package leaflet: Information for the patient

Minoxidil POA Pharma Tablets (Minoxidil POA Pharma 2.5 mg Tablets) (Minoxidil POA Pharma 10 mg Tablets) minoxidil

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 POA Pharma 2.5 mg or 10 mg Tablets, but it will be referred to as Minoxidil POA Pharma Tablets throughout this leaflet.

What is in this leaflet

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

This medicine is prescribed by your doctor to lower your blood pressure and belongs to a group of medicines called antihypertensive drugs. The active substance is minoxidil.

Minoxidil POA Pharma Tablets are used, when other medicines – even in combination (usual triple combination) – cannot achieve adequate blood pressure control (therapy-resistant hypertension).

Minoxidil POA Pharma Tablets should be given in conjunction with a medicine to help your body get rid of excess water (diuretic) and a medicine to inhibit the effect of adrenaline (beta-blocker) (see section 2).

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

Do not take Minoxidil POA Pharma Tablets

- If you are allergic (hypersensitive) to minoxidil or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from high blood pressure in the pulmonary circulation (pulmonary hypertension) due to a narrowing of the valve opening between the left atrium and the left ventricle (Mitral stenosis).
- If you have a tumour of the adrenal medulla (phaeochromocytoma).

Talk to your doctor if any of the above apply to you, as you must not take Minoxidil POA Pharma Tablets in this situation.

Warnings and precautions

Talk to your doctor or pharmacist before using Minoxidil POA Pharma Tablets:

If you have had a heart attack (myocardial infarction), you should not receive Minoxidil POA Pharma Tablets until your condition has been stabilised.

Minoxidil POA Pharma Tablets can make your heart beat too fast and may lead to sudden pain in the chest (angina pectoris). Therefore, it is necessary to use Minoxidil POA Pharma Tablets together with drugs that counteract such a response (beta-blockers or other sympathetic nervous system suppressants). If you suffer from angina pectoris, minoxidil should be used with caution.

Shortly after starting minoxidil therapy, approximately 60 % of patients exhibit ECG alterations (altered direction and magnitude of the T waves).

These changes usually disappear with prolonged minoxidil treatment and are reversible when minoxidil is discontinued.

In about 3 % - 5 % of minoxidil treated patients not on dialysis, abnormal changes in the pericardium have been observed (pericardial effusions, occasionally with tamponade). The pericardial effusions occurred mainly in patients who had insufficient or impaired kidney function or other pre-existing severe conditions. Your doctor may therefore carefully monitor you for any signs of pericardial effusion and pericardial complaints.

Minoxidil POA Pharma Tablets are not recommended for the treatment of mild or unstable high blood pressure.

Effect on the salt and water balance:

When you receive Minoxidil POA Pharma Tablets you may notice physical signs that water accumulates in your body (oedema formation) or you may experience a deterioration of an existing cardiac impairment. This happens to a greater extent when Minoxidil POA Pharma Tablets are used without additional medications. It is therefore necessary to take Minoxidil POA Pharma Tablets together with a diuretic, which removes extra salt and water from your body.

Pay attention that you follow a low salt diet.

You should weigh yourself daily and keep an accurate record of your weight while you are taking this medicine. If you rapidly gain weight by 2 kg or more, or you notice swelling of the face, eyelids or hands, or ankles, or in the stomach area, this could be a sign of increased water retention. Your doctor may need to change the dose of your medicines.

Body weight gain in the range of 1 to 1.5 kg often occurs in the beginning of the treatment. This usually disappears when you continue the treatment. The extra water and salt in your body (more than 1 to 1.5 kg) may reduce the effectiveness of Minoxidil POA Pharma Tablets.

Your doctor should carefully explain to you how to comply with the diuretic therapy.

If you have impaired kidney function that does not require cleaning your blood (dialysis), it is particularly important to control the salt and water balance when you are under treatment with Minoxidil POA Pharma Tablets.

If you have kidney failure or are on dialysis, you may need a lower dose of Minoxidil POA Pharma Tablets.

Most of the patients taking Minoxidil POA Pharma Tablets experienced an extension, a color intensification and thickening of the fine body hair in various areas of the body. This was observed

about 3 to 6 weeks after the start of treatment. First, the hair growth becomes visible in the forehead, the temples, between the eyebrows or the upper part of the cheeks and later the hair growth is intensifying on the back, arms, legs or scalp. Some patients hardly notice the increase in the hair growth. However, women and children often feel bothered about this. Unwanted hair can be removed with shaving or through hair removal products. The increased hair growth disappears one to six months after stopping treatment with Minoxidil POA Pharma Tablets.

Do not stop the treatment with Minoxidil POA Pharma Tablets because of this side effect. Talk to your doctor. While these side effects can be annoying, they are not dangerous.

Rarely, there has been a decrease in blood components (thrombocytopenia, leukopenia).

Other medicines and Minoxidil POA Pharma Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Other antihypertensive drugs (e.g., guanethidine, betanidine) may interact with Minoxidil POA Pharma Tablets by causing blood pressure to drop too low. It is possible that your body cannot adjust the blood pressure properly while sitting or standing (orthostasis).

Hence your doctor may recommend you to stop these therapies a few days before starting treatment with Minoxidil POA Pharma Tablets. If this is not feasible, your treatment should be instituted in the hospital under careful monitoring.

Antipsychotic drugs (neuroleptics)

An increased antihypertensive effect has been observed with concomitant administration of minoxidil and neuroleptics.

Water tablets (diuretics)

The water retention in the body caused by Minoxidil POA Pharma Tablets can be reduced by additional administration of diuretics.

Drugs that slow down your heartbeat and reduce force and excitability of your heart (beta blockers)

The increased pulse caused when Minoxidil POA Pharma Tablets are used alone is effectively suppressed by beta-blockers.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

There are limited data from the use of minoxidil in pregnant women.

Minoxidil is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

Minoxidil has been reported to be excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from minoxidil therapy. The benefit of breast-feeding for the child and the benefit of therapy for the woman must be weighed.

Fertility

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

Driving and using machines

No studies on the effect of minoxidil on the ability to drive or use machines have been performed. The ability to drive or operate machinery may be influenced dependent on your individual response to treatment, particularly at the start of therapy.

Minoxidil POA Pharma 2.5 mg, 10 mg Tablets contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these medicines.

3. How to take Minoxidil POA Pharma 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.

Your doctor will usually prescribe two other medicines together with Minoxidil POA Pharma Tablets. These will assist in lowering your high blood pressure and in suppressing the undesirable effects of Minoxidil POA Pharma Tablets.

If the blood pressure is lowered by a drug such as Minoxidil POA Pharma Tablets, the body will try to restore the blood pressure to its original levels. This is achieved by water retention in the body (the heart then has more fluid to pump) and by making your heartbeat faster.

To avoid these problems, your doctor will normally prescribe you water tablets (diuretic) and another medicine (beta-blocker) to decrease your heartbeat (pulse).

The regular administration of Minoxidil POA Pharma Tablets and the other medicines is absolutely necessary for your condition. Do not change the dose of Minoxidil POA Pharma Tablets and the other medicines. Talk to your doctor.

Dose adjustments of minoxidil should be done in a special outpatient department or clinic. Regular monitoring must be guaranteed. The diuretic must be titrated in such way that no weight gain can occur as a result of increased water accumulation in the tissue (water retention).

How many Minoxidil POA Pharma Tablets to take

Unless otherwise prescribed by the doctor the usual dose is as follows:

Adults and children over the age of 12

The usual starting dose of Minoxidil POA Pharma Tablets for adults and children aged over 12 years is 5 mg minoxidil (2 tablets of 2.5 mg or ½ tablet of 10 mg) per day.

If necessary, your doctor might increase your dose.

There should be at least three days between each increase of dose.

Use in children up to 12 years

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 additionally receive other medicines at the discretion of 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 symptoms: 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.

What is the maximum daily dose

A maximum daily dose of 100 mg minoxidil in adults and 50 mg minoxidil in children should not be exceeded.

In patients with severe renal impairment (creatinine clearance less than 30 ml/ min) or in the case of patients on dialysis, the required dose may be lower. Minoxidil POA Pharma Tablets should be administered after dialysis or at least 2 hours before dialysis.

The dose may be adjusted in patients with impaired liver function. Therapy can be initiated with a reduced dose once daily and then titrated up, until the desired therapeutic effect is achieved with the lowest effective dose.

Minoxidil POA Pharma Tablets are available in different strengths. Please pay attention to the appearance of the tablets (see “What Minoxidil POA Pharma Tablets looks like and contents of the pack”).

At the beginning of the treatment with Minoxidil POA Pharma Tablets, your doctor will need to see you more often to determine the right dose for you. Take your medicine in accordance with the dosage scheme prescribed by your doctor.

If you are being treated by more than one doctor, inform all your doctors that you are a hypertensive patient treated with Minoxidil POA Pharma Tablets.

Method of administration

Oral administration.

Swallow Minoxidil POA Pharma Tablets whole with a sufficient amount of water.

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

The 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.

Duration of treatment

There is no specific time limit. The duration of the treatment depends on your condition. Please discuss this with your doctor.

Please talk to your doctor or pharmacist if you have the impression that the effect of Minoxidil POA Pharma Tablets is too strong or too weak.

If you take more Minoxidil POA Pharma Tablets than you should

If you accidentally take more Minoxidil POA Pharma Tablets than you should the most common side effect is low blood pressure. Occasionally, lower urine volume has been described. Tell your doctor or pharmacist straight away, if you have taken too many tablets.

If you forget to take a dose of Minoxidil POA Pharma Tablets

Do not skip a dose. If you forget to take a dose, do not take an extra dose to make up for the forgotten dose, but take the next dose at the normal time as prescribed.

If you stop taking Minoxidil POA Pharma Tablets

Do not interrupt or stop taking Minoxidil POA Pharma Tablets or the additional medicines you are currently taking without consulting your doctor first.

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.

As a rule, if you take Minoxidil POA Pharma Tablets you may experience a reduction of pre-existing side effects attributable to your disease or previous therapy.

Potential side effects of Minoxidil POA Pharma Tablets are:

Very common: may affect more than 1 in 10 people

Increased heart rate (tachycardia), inflammation of the lining that surrounds the heart (pericarditis), abnormal electrocardiogram (ECG), increased hair growth (hypertrichosis), hair color changes.

Common: may affect up to 1 in 10 people

Accumulation of fluid around the heart (pericardial effusion), compression of the heart due to a build-up of fluid (pericardial tamponade), accumulation of fluid in the tissue (salt and water retention), oedema, gastrointestinal intolerance.

Uncommon: may affect up to 1 in 100 people

Accumulation of fluid between the layers of tissue that line the lungs and chest cavity (pleural effusions), breast tenderness.

Rare: may affect up to 1 in 1,000 people

Decrease in white blood cells (leukopenia), reduction in blood platelets (thrombocytopenia), which increases risk of bleeding or bruising, also in individual cases shortened lifespan of certain blood components (hemolytic anemia), allergic reactions, antinuclear antibodies, intolerance with regard to certain types of sugar (glucose intolerance), chest tightness, new or worsening pain in chest, arms, shoulders or upper abdominal discomfort (angina pectoris), too low blood pressure (hypotension) related to previous or concomitant use of guanethidine (used to treat high blood pressure or for local blockage of a nerve), pulmonary infiltrates, nausea, serious feverish illness with inflammation and blistering of the skin and mucosa, e.g. affecting mouth, nose or genitals (Stevens-Johnson syndrome), inflammation and blistering of the skin (bullous dermatitis), rash, enlargement of the breast in men (gynecomastia), increase in liver enzymes.

Not known: frequency cannot be estimated from the available data

Dizziness, drowsiness, feeling weak, difficulty breathing, especially when lying down, severe and possibly life-threatening skin reactions (toxic epidermal necrolysis), swelling of the ankles, feet or fingers with or without weight gain, reduced kidney function resulting in increased creatinine and urea levels in your blood, haematocrit decreased, haemoglobin decreased.

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 national reporting system listed in ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minoxidil POA Pharma 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 POA Pharma Tablets contains

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

What Minoxidil POA Pharma Tablets looks like and contents of the pack

Minoxidil POA Pharma 2.5 mg Tablets are round, white to off white tablets, approximately 5.5 mm in diameter, with score line on one side and “2.5” engraved on the other side.

Minoxidil POA Pharma 10 mg Tablets are round, white to off white tablets, approximately 9 mm in diameter, with score line on one side and “10” engraved on the other side.

Your tablets are supplied in blister strips of 10 tablets in cartons containing 30 or 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

POA Pharma Scandinavia AB
Hyllie Stationstorg 31, vån 5,
215 32 Malmö
Sweden

Manufacturer

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

This medicine is authorised in the Member States of the European Economic Area under the following names:

Germany	Minoxidil POA Pharma 2,5 mg Tabletten
	Minoxidil POA Pharma 10 mg Tabletten
Malta	Minoxidil POA Pharma 2.5 mg Tablets
	Minoxidil POA Pharma 10 mg Tablets

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