

Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations)-1986

This medicine can be sold without a physician's prescription

Special warnings about using this medicine

Consult your physician or pharmacist in the following cases:

- if you are unsure whether the skin on your scalp is healthy and not damaged.
- if you suffer from heart disease, including abnormal heart rhythms or rates, angina or chest pains and/or circulation disorders.

Additional warnings

• If Minoxidil passes into the blood stream, it can cause some side effects due to low blood pressure such as chest pain, rapid heart beat, faintness, dizziness, swollen hands and feet, persistent redness or irritation of the scalp. If you experience any of the side effects in this list, stop using the medicine and contact your physician.

When using the medicine as recommended, it is extremely unlikely that these side effects will occur. However, there is a chance the medicine could get into the blood stream if it is over used or if there is a scalp condition such as psoriasis. Therefore it is very important that you use the medicine as recommended and follow the instructions very carefully. See section 3.

- Warning: Flammable liquid. Keep away from heat/sparks/open flame/hot surfaces. Do not smoke in its vicinity. Avoid exposure of the container and its contents to open flames during use, storage and disposal. Keep container tightly closed. Store in a well-ventilated place.
- Avoid contact with the eyes, mouth, damaged skin and sensitive areas. If the solution is accidentally applied to areas of the body other than the scalp, rinse the areas thoroughly with plenty of water.
- Do not apply to areas of the body other than the scalp.
- Accidental ingestion may cause serious cardiac side effects. Therefore this product has to be kept out of the reach of children.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your physician or pharmacist. Especially inform the physician or pharmacist if you are taking drugs of the following classes:

- certain blood pressure medicines (vasodilators) - widen blood vessels, such as hydralazine. There is a risk that Minoxidil, the active ingredient in the medicine, will interact with these medicines and increase their effect.

If you are not sure about the medicine you are using, show the pack to a pharmacist.

If any of the sections above apply to you now or in the past, **consult your physician or pharmacist.**

Smoking

This medicine is flammable, therefore do not smoke in its vicinity.

Pregnancy, breast-feeding and fertility

This medicine is intended only for men and is not intended for use by women. There is no information about the effect of using the medicine on fertility.

Driving and using machines

This medicine may cause dizziness or low blood pressure. If you experience these side effects do not drive or operate machinery.

Important information about some of the ingredients of this medicine

The medicine contains approximately 523 mg propylene glycol per 1 ml solution which may cause scalp skin irritation.

The medicine also contains approximately 258 mg alcohol per 1 ml solution, equal to 25.8% W/W, which may cause a burning sensation and irritation if it has come in contact with damaged skin or gets into your eye. If this medicine gets in your eye or mouth or has come in contact with a cut or damaged skin, wash the area with cold running tap water.

3. How to use this medicine?

Check with your physician or pharmacist if you are not sure about the dosage and treatment regimen.

The medicine is for topical and external use only, and should be applied directly to the scalp.

The usual recommended dosage is:

The maximum amount for treatment is 2 ml a day: 1 ml in the morning and 1 ml in the evening (1 ml = 7 sprays). There should be at least 12 hours interval between each use.

Frequent use and/or use of a larger amount will not increase hair growth, but may cause more side effects. Therefore, **make sure to measure the dose by the recommended number of sprays.**

Do not exceed the recommended dose.

On a completely dry scalp and hair, use a total amount of 1 ml of the medicine on all bald areas. If possible, start at the center of the bald area and with a clean finger spread the product. After application, wash your hands and any area that has come in contact with the solution thoroughly. Avoid allowing the medicine to drop on the face or on areas of skin outside the bald areas. If it accidentally spills on an area that is not the scalp, rinse well with plenty of water. Avoid breathing in the spray whilst applying to the scalp.

After using the medicine: Avoid washing your hair for about two hours. Do not use a hair dryer to dry the solution on your hair faster. Do not rest your head on a pillow for at least one hour after applying it on your scalp. Avoid exposing your hair to the sun.

How to use:

- Remove the plastic cap, replace with the spray applicator and screw on.



- Hold the bottle vertically, spray the solution on the affected area and use your fingertips to spread it over the desired area. The total amount of solution used (on all bald areas together) shall not exceed 7 sprays.



- Wipe the spray applicator after use.

After application, always wash your hands thoroughly, and if the solution is accidentally applied to areas of the body other than the scalp, rinse the areas thoroughly with plenty of water.

How can you contribute to the success of the treatment?

Apply the medicine only when the scalp and hair are completely dry. Adhere to the treatment according to the instructions.

Users who are younger and/or who have been losing hair for a short period of time and/or have a small area of baldness may experience better results. If the balding process started many years ago and/or the bald area is extensive, the likelihood of treatment success is low.

Continued use of the medicine

- You may need to use this medicine twice daily for at least two months before you see new hair growth, this is because hair growth is a slow process.
- Hair growth may be soft and downy at the start but should eventually become the same as normal hair.
- Once the hair has begun to re-grow, you need to continue using this medicine twice a day for the growth to continue. In clinical trials with Minoxidil, 3 out of every 5 men reported hair re-growth after 48 weeks of continual use of this medicine.
- When you stop using the medicine, the hair that has re-grown may disappear after 3-4 months and the hair loss and balding process will continue.
- If you experience no improvement in your hair growth after one year of use, you should discontinue treatment.
- If at any time during your treatment you are concerned, you should consult your physician or pharmacist.

If you have accidentally taken an overdose, or if a child or adult has accidentally swallowed some medicine, proceed immediately to a physician or to a hospital emergency room and bring the medicine package with you (with the medicine bottle, as the physician may like to have some idea of how much of the medicine was swallowed).

If you forget to apply a dose of the medicine

If you miss one or two applications, just carry on as normal as if you had not missed the dose - **do not use twice as much or twice as often.**
Note: Do not swallow. This medicine is intended for external use on the scalp only. Avoid breathing spray mist. Swallowing the medicine may lead to serious heart function problems.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, the use of the medicine may cause side effects in some users. Do not be alarmed when reading the list by this list of side effects. You may not experience any of them.

If you experience any of the following side effects, stop using the medicine and contact your physician immediately:

- Chest pain.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

If you experience any of the following side effects, stop using the medicine and consult your physician:

- Allergic reactions including swollen face, skin redness or itching or throat tightness.
- Low blood pressure.
- Fast heart beat or an increased awareness of the heart beat (palpitations).
- Feeling faint or dizzy.
- Swollen hands or feet, shortness of breath.
- Sudden unexplained weight gain.
- Persistent local redness or rash.

Temporary hair loss may occur at the beginning of treatment (first 2-6 weeks of treatment). This phenomenon is likely to be as a result of a change within the growth cycle and it should stop within two weeks. If this hair loss continues for longer than two weeks, stop using the medicine and talk to your physician.

Change in hair texture (rare - may affect up to 1 in 1,000 users) or change in hair color (frequency unknown). If this happens, you should stop using the medicine.

Additional side effects

Very common side effects (may affect more than one in 10 users):

- Headache

Common side effects (may affect up to 1 in 10 users):

- Unwanted growth of non scalp hair including facial hair growth.
- Itching or inflammation of the skin (dermatitis)

Uncommon side effects (may affect up to 1 in 100 users):

- Nausea

Side effects of unknown frequency (the frequency of these effects has not been determined yet):

- Depressed mood
- Eye irritation
- Vomiting
- Scalp irritation such as local redness, dryness and flaky skin. This may be due to propylene glycol in the medicine. This is usually only a temporary effect, but if it is persistent, you should stop using this medicine.
- Acne-like rash, itchy rash, blistering, bleeding or ulceration.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your physician.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link 'Reporting Side Effects from Drug Treatment' that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis Israel Pharmaceuticals via the following address: Padagis.co.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and bottle. The expiry date refers to the last day of that month.
- Store below 25°C.
- The product is flammable. Keep away from flame and/or heat source. Do not light a cigarette or expose yourself to a flame until the product has dried completely.
- After first opening, the medicine may be used for up to a month, but not later than the expiry date appearing on the package of the medicine.

6. Additional information

- In addition to the active ingredient, this medicine also contains: Propylene glycol, alcohol, purified water
- What the medicine looks like and contents of the pack:
The pack contains 1 or 2 bottles. Each bottle contains 60 ml solution. The pack also contains a spray applicator.
- Revised in June 2023 according to MOH guidelines.
- Registration number of the medicine at the National Drug Registry of the Ministry of Health: 144-70-33300
- Manufacturer and registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

Noxidil 5%

Solution for topical treatment of the scalp

Composition:

Active ingredient: Minoxidil 5% W/W.

Inactive ingredients and allergens in the medicine: see section 2 under "Important information about some ingredients of this medicine", and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, contact your physician or pharmacist.

You must use this medicine according to the instructions in this leaflet. Consult your pharmacist if you need further information.

Contact a physician if the symptoms of your illness get worse or if they do not improve.

The medicine is intended for men aged 18-65 years in cases of hereditary hair loss only.

If you experience no improvement in your hair growth after one year of use, you should discontinue treatment.

1. What is this medicine intended for?

The medicine is intended for scalp hair growth in healthy men aged 18-65 years, in cases of hereditary-type balding only. Consult the attending physician to confirm that your type of hair loss is suitable for treatment with this medicine.

Therapeutic group: vasodilators, for topical application, for treatment of hair loss.

The medicine contains Minoxidil, which is considered a substance that works by helping the blood flow to the scalp hair follicles.

- The medicine works best in men with hair loss or thinning at the top of the scalp.
- Those who are young men, men who have been losing hair for a short period of time or have a small area of baldness are likely to experience the best results.
- You are unlikely to benefit from the medicine if you have been bald for many years or have a large area of baldness.

Hereditary hair loss is recognizable according to the following signs:

- The pattern of hair loss (see diagrams).
- It starts gradually and progresses.
- You have a family history of hair loss.
- No other symptoms are present with your hair loss.



What you need to know before you use this medicine

This medicine is suitable for most people, but certain people must not use it. If you have any doubt, talk to your physician or pharmacist.

2. Before using this medicine

Do not use this medicine if:

- you are a woman.
- you are under the age of 18 or over the age of 65.
- you are sensitive (allergic) to the active ingredient Minoxidil or to any of the other ingredients this medicine contains (see section 6).
- you are not sure if your hair loss is of hereditary origin.
- your hair loss is caused by drug treatment.
- you have total baldness or complete loss of all body hair.
- the cause of your hair loss is unknown, or it is sudden and unexpected.
- you have high blood pressure, even if it is not being treated.
- you have any condition that affects your scalp skin (such as sunburn, psoriasis etc.).
- you shave your scalp.
- you are using creams, ointments or lotions used to treat scalp conditions, such as: Dithranol - used to treat psoriasis, Tretinoin - used to treat acne or other skin disorders, Corticosteroids - anti-inflammatory substances, Petrolatum - a common ingredient in hair wax or gel.
- you have any kind of dressing or bandage on your scalp.
- you are not sure whether the skin of your scalp is healthy and normal.

If any of these bullet points apply to you now or in the past, consult a physician or pharmacist before using this medicine.