

Hairgain® Foam

Active ingredient: Minoxidil 5% w/w

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

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. Use the medicine according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information.

Refer to the doctor if the symptoms worsen or do not improve after 16 weeks.

- The preparation is intended for men aged 18-49 years in cases of hereditary hair loss only.
- The preparation is intended for men only and is **not** intended for use in women.
- Do not apply the preparation to other areas of the body other than the scalp. If accidentally applied, rinse thoroughly with a large amount of water (see section 2).
- **The preparation is intended for external use on the scalp area only.**
- The preparation is flammable and should be used very carefully.

1. WHAT IS THE MEDICINE INTENDED FOR?

Hairgain Foam is intended for hair re-growth treatment in men.

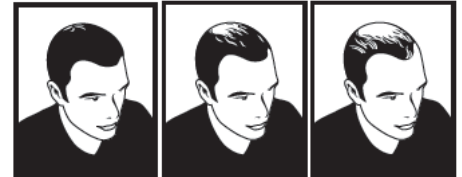
Therapeutic class: vasodilator for local administration, for the treatment of hair loss.

The preparation contains the active substance minoxidil, which aids the blood flow to the hair follicles on the scalp.

- The preparation is intended for use in men aged 18-49 in cases of hereditary hair loss only.
- Consult the attending doctor to ensure that your type of hair loss is suitable to be treated with this preparation.
- Hairgain Foam is mainly effective in men whose hair loss or hair thinning is at the top of the scalp.
- Young users who have been losing hair for a short period of time or whose area of baldness is small are expected to see the best results.
- Users whose baldness started many years ago or who have a large area of baldness are unlikely to benefit from the treatment.

Hereditary hair loss is recognizable by:

- The pattern of baldness (see illustration).
- Hair loss that starts gradually and progresses.
- A family history of hair loss.
- Absence of other symptoms accompanying the hair loss.



2. BEFORE USING THE MEDICINE:

Do not use Hairgain Foam if:

- You are sensitive (allergic) to the active ingredient minoxidil or to any of the additional components the medicine contains. For a list of inactive ingredients, refer to section 6 "Additional information".
 - You are a woman.
 - You are under the age of 18 or above the age of 49.
 - Your hair loss is caused by a medicinal treatment.
 - You have total baldness or you suffer from complete loss of all body hair.
 - The cause of baldness is unknown, or it is sudden and unexpected.
 - You suffer from high blood pressure, even if you are not being treated.
 - You suffer from any condition that affects your scalp, including sunburns and psoriasis.
 - You have a shaved scalp.
- You are using creams, ointments or lotions to treat scalp conditions, such as:
- Dithranol – to treat psoriasis
 - Tretinoin – to treat acne or other skin problems
 - Corticosteroids – a type of anti-inflammatory preparations
 - Petrolatum – a common ingredient found in hair wax or gel.
- You have any kind of dressing on the scalp.
 - Do not use the preparation unless you know that your scalp is normal and healthy.

If any of the above applies to you now or applied to you in the past, consult a doctor or pharmacist before using the preparation.

Special warnings regarding the use of the medicine

Before using Hairgain Foam, tell the doctor or pharmacist if:

- You are unsure whether your scalp is normal and healthy.
- You suffer from a heart disease, including irregular heart rate, angina or chest pains and/or blood circulation disorders.

Special warnings regarding the medicine Hairgain Foam

- If the active ingredient minoxidil penetrates the bloodstream, it may cause certain side effects related to low blood pressure, such as: chest pain, rapid heartbeat, faintness, dizziness, swollen hands and feet, persistent redness or

irritation of the scalp. If you experience any of the side effects mentioned, stop using the preparation and inform the doctor.

When the preparation is used according to the recommended instructions, it is very unlikely that these side effects will occur. However, there is a chance that the preparation may penetrate the bloodstream if it is overused or in cases of scalp conditions such as scalp psoriasis. Therefore, it is very important to use the preparation exactly as instructed (see section 3 "How should you use the medicine?").

- **Danger!** The aerosol is extremely flammable. The pressurized container may burst if heated. Keep the container away from heat, hot surfaces, sparks, open flames and ignition sources. Do not smoke. Do not spray on an open flame or on other ignition sources. Do not pierce or burn the container, even after use. Protect the container from sunlight. Do not expose the container to temperatures over 50°C.
- Avoid contact of the preparation with the eyes, mouth, broken skin and sensitive areas of the body. If the foam is accidentally applied to an area of the body other than the scalp, rinse thoroughly with plenty of water.
- Do not use the preparation on other areas of the body other than the scalp.
- Exceeding the recommended dosage will **not** re-grow hair more quickly and may cause a higher risk of side effects.
- Cases of excessive hair growth on the body of infants due to contact with the area treated with minoxidil in adults have been reported. After the exposure to minoxidil ended, the infants' hair growth returned to normal. Ensure that children do not come in contact with areas of your body that are treated with minoxidil. Consult a doctor if you notice excessive hair growth in your child during treatment with a topical minoxidil product.
- **Caution! Flammable substance, keep away from fire. Do not light a cigarette or expose yourself to fire until the preparation has completely dried.**

Smoking

The preparation is flammable; therefore, you should not smoke near it.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Certain medicines for treatment of blood pressure from the class of vasodilators, such as hydralazine. There is a potential risk that minoxidil will increase their effect.

Pregnancy, breastfeeding and fertility:

The preparation is **not** intended for women, but for men only. Do not use this preparation if you are pregnant or breastfeeding.

Driving and operating machinery:

The preparation 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 the medicine

Some of the ingredients of the preparation may cause problems:

- Ethanol (alcohol) – the preparation contains 578 mg alcohol in every 1 gram of foam, which may cause a burning sensation on damaged skin as well as irritation in contact with the eyes. In case of contact with the eyes, mouth, a cut in the skin or wounded skin, wash the area with plenty of cold tap water.
- Cetyl alcohol and stearyl alcohol – may cause local skin reactions such as contact dermatitis.
- Butylated hydroxytoluene – may cause local skin reactions such as contact dermatitis or irritation to the eyes and mucous membranes.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen.

The usual recommended dosage is: On a completely dry scalp, apply 1 gram (equivalent to the volume of half a capful) to the total affected area twice daily.

Leave at least 12 hours between each use. Do not exceed 2 grams in a day.

Do not use more than twice a day.

Frequent use and/or use of a larger quantity will not increase the hair growth but may cause more side effects.

Do not exceed the recommended dose.

Duration of treatment

Continuous use of Hairgain Foam: you may need to use the medicine twice a day for at least 8 weeks before you notice new hair growth. This is because the process of hair growth is slow and continuous. The growing hair will be soft and downy at the start, but should eventually become similar to your normal hair. Once the hair has begun to re-grow, continue treatment twice a day for the hair growth to continue. If there is no improvement in your hair growth after 16 weeks of use, you should stop the treatment. The efficacy of the preparation in clinical studies has not been tested beyond 16 weeks.

Consult the doctor or pharmacist if you have any question.

Method of use:

- **Do not swallow. For external use only.**
- Apply directly only to the scalp area.
- Do not use on other body parts other than the scalp.
- Wash your hands thoroughly before and after using the foam and thoroughly rinse other areas that have come into contact with the foam.

- Make sure the hair and scalp are completely dry before using the foam.
- Remove the container's cap, turn the container upside down and press the spray nozzle to dispense foam onto your fingers. The required amount should not exceed 1 gram (the volume of half a capful).
- The foam may melt on contact with warm skin. If your fingers are warm, rinse them well with cold water first. Be sure to dry them thoroughly before use.
- Spread the foam onto the scalp using your fingers and gently massage it into the areas of baldness.
- Afterwards, wash your hands thoroughly.
- After using the medicine: avoid washing your head for about two hours. Do not use a hair dryer to speed up hair drying. Do not place your head on the pillow for at least one hour after application on the scalp. Avoid exposing your hair to the sun.



Remove the cap



Turn the container upside down and press the spray nozzle



Massage the scalp

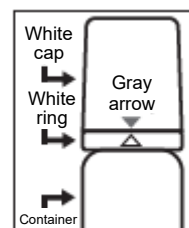
Instructions for opening and closing:

To open:

1. Hold the ring (see diagram).
2. While holding the ring, turn the cap so that the arrow on the container matches the arrow on the cap.
3. Remove the cap.

To close:

1. Place the cap on the container and turn it until you hear a click.
2. Make sure the arrows are not aligned, so that the container remains protected from being opened by children.



If you accidentally used a higher dosage

If you took an overdose or if a child or someone else accidentally swallowed this medicine, proceed immediately to the doctor or to a hospital emergency room and take the package of the medicine with you.

If you forget to use the medicine at the designated time, continue the treatment as usual. Do not use a double dose. Even if there is an improvement in your condition, do not stop treatment with the medicine without consulting the doctor

How can you contribute to the success of the treatment?

Follow the treatment according to the instructions. Discontinuation of treatment will most likely cause loss of the hair that has grown and renewal of the hair loss process within 3-4 months.

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

If you have any other questions regarding use of the preparation, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Hairgain Foam may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using the medicine and seek immediate medical assistance if you feel:

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

Stop using the medicine and consult a doctor if you suffer from:

- Allergic reactions including swollen face, skin redness or itching, or throat tightness
- Low blood pressure
- Fast heartbeat or feeling of strong heartbeats (palpitations)
- Fainting or dizziness
- Swollen hands and feet, shortness of breath
- Sudden and unexplained weight gain
- Persistent local redness or rash

Very common side effects (occur in more than 1 user out of 10)

- Headache

Common side effects (occur at a frequency of up to 1 user out of 10)

- Itching or dermatitis
- There have been reports of unwanted non scalp hair growth (including facial hair growth in women)
- Always make sure to wash your hands thoroughly after using the preparation. If foam is accidentally applied to body parts other than the scalp, rinse the area thoroughly with plenty of water

Uncommon side effects (occur at a frequency of up to 1 user out of 100)

- Nausea

Rare side effects (occur at a frequency of up to 1 user out of 1,000)

- Change in hair texture may occur. In this case, stop using the preparation

Additional side effects which may occur and whose frequency is not known:

- Depressed mood

- Eye irritation
- Vomiting
- There have been reports of scalp irritation, such as local redness, dryness and flaky skin. These effects may be caused by the additional ingredients of the preparation: butylated hydroxytoluene, cetyl alcohol and/or stearyl alcohol. These side effects are usually temporary, but if they are persistent, you should stop using the medicine
- Acne-like rash, itchy rash, blistering, bleeding or ulceration
- Temporary hair loss may occur during the first 2-6 weeks of treatment; this process is probably due to a change in the growth cycle and should stop within a couple of weeks. If hair loss continues for longer than two weeks, stop using the medicine and consult the doctor
- In case of a change in hair color or texture, stop using the medicine

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

In addition, report to the company using the following address: Padagis.co.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) appearing on the package and container. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Caution! Flammable substance, keep away from fire.

6. ADDITIONAL INFORMATION:

In addition to the active ingredient, the preparation also contains:

Dehydrated alcohol, Purified water, Lactic acid, Cetyl alcohol, Stearyl alcohol, Polysorbate 60, Butylated hydroxytoluene, Citric acid, Hydrocarbon Mixture Type PIB 5515

- The foam contains 578 mg alcohol in every 1 gram of foam.
- What Hairgain Foam looks like and the content of the package: Hairgain Foam is a creamy-white foam, packed in a 60-gram metal container (spray), the carton package contains one container or two containers. Not all package sizes may be marketed.
- Name of license holder and manufacturer: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in February 2025 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 151.07.33885

Hairgain is a registered trademark of Padagis Israel Pharmaceuticals Ltd.