

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

This medicine can be sold without a doctor's prescription

# Hairgain Foam

### Active ingredient: Minoxidil 5%

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

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

- Refer to the doctor if the symptoms of your illness worsen or do not improve after 16 weeks.
- The product is intended for men aged 18-49 years in cases of hereditary hair loss only.
- The product is intended for men only **and is not** intended for use in women.
- Do not apply the product to areas of the body other than the scalp. If accidentally applied, rinse thoroughly with plenty of water (see section 2).
- **The product is intended for external use on the scalp area only.**
- The product is flammable and should be used very carefully.

## 1. What is the product intended for?

Hairgain Foam is intended for growth of scalp hair in men.

**Therapeutic group:** Vasodilator, upon topical administration, for the treatment of hair loss.

The product contains the active ingredient minoxidil, which is thought to work by aiding blood flow to the hair follicles of the scalp.

- The product is intended for men aged 18-49 years in cases of hereditary hair loss only.
- Consult the attending doctor to ascertain that your type of hair loss is suitable for treatment with this product.
- Hairgain Foam is effective mainly in men whose hair loss or thinning at the top of the scalp.
- Young users who have begun losing hair recently or have a small area of baldness, are expected to see the best results.
- Users whose hair loss began many years ago or have a large area of hair loss, are unlikely to benefit from the treatment.

**Hereditary hair loss** can be identified by:

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



## 2. Before using the product:

- Do not use Hairgain Foam if:
    - you are hypersensitive (allergic) to the active ingredient minoxidil or to any of the other ingredients this product contains.
    - you are a woman.
    - you are under the age of 18 or over the age of 49.
    - your hair loss was caused by medicinal treatment.
    - you have total baldness or if you suffer from complete loss of all body hair.
    - the cause of the hair loss 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 problems, such as:
      - Dithranol - for the treatment of psoriasis
      - Tretinoin - for the treatment of acne or other skin disorders
      - Corticosteroids - a type of anti-inflammatory
      - Petrolatum - a common ingredient that is found in hair wax or gel
    - you have any type of dressing on your scalp.
    - Do not use the product unless you know that your scalp is in a normal and healthy condition.

If any of the bullet points above apply to you now or in the past, consult a doctor or pharmacist before using the product.

**Special warnings regarding the use of the medicine**

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

- you are unsure if your scalp is normal and healthy.

or suffer from heart disease, including abnormal heart rhythm, angina or chest pains and/or blood circulation problems.

**Special warnings regarding the product Hairgain Foam:**

- If the active ingredient minoxidil passes into the blood stream, 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 these side effects, stop using the product and inform the doctor. When the product is used according to the recommended instructions, it is extremely unlikely that these side effects will occur. However, there is a chance that the product may get into the blood stream if it is over used or in cases of scalp problems such as psoriasis on the scalp. Therefore, it is very important to use the product exactly according to the instructions (see section 3).
- **Danger!** The aerosol is extremely flammable. The pressurized canister may explode if it is heated. Keep the canister away from heat, hot surfaces, sparks, open flames and ignition sources. Do not smoke. Do not spray on an open flame or another ignition source. Do not pierce or burn the canister even after use. Protect from sunlight. Do not expose the canister to a temperature above 50°C.
- Avoid contact of the product with the eyes, mouth, broken skin and sensitive areas of the body. If the foam is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water.
- Do not use the product on areas of the body, other than the scalp.
- Exceeding the recommended dose will **not** re-grow the hair more quickly and may cause an increased risk of getting side effects.
- **Warning! Flammable material, protect from fire. Do not light a cigarette or be exposed to fire until the product has completely dried.**

### Smoking

The product is flammable, therefore do 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 pharmacist.** Especially if you are taking:

- Certain blood pressure medicines from the vasodilator group such as hydralazine.

There is a potential risk that minoxidil will increase their effect.

### Pregnancy and breastfeeding

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

### Driving and using machines

The product 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

Some of the ingredients of the product may cause problems:

- **Ethanol (alcohol)** – the product contains 570 mg alcohol per 1 gram of foam which may cause a burning sensation on damaged skin, as well as irritation upon contact with the eyes. In case of contact with the eyes, mouth, a cut on the skin or damaged skin, wash the area with plenty of cool tap water.
- **Cetyl alcohol and stearyl alcohol** – may cause local skin reactions such as contact dermatitis.
- **Butylated hydroxytoluene** – may cause local skin reactions (e.g., contact dermatitis) or irritation to the eyes and mucus membranes.

## 3. How to use the product

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the product.

The usual recommended dosage is: 1 gram (the volume of half a capful) on a completely dry scalp, on the balding area, twice a day.

Leave an interval of at least 12 hours between one use and the next. 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

Prolonged use of Hairgain Foam: You may need to use the product twice a day for at least 8 weeks, before you notice new hair growth. This is because the hair growth process is slow and lengthy. The hair that grows will be soft and downy at the beginning, but should eventually become similar to the regular hair. Once the hair has begun to grow continue the treatment twice a day, so that the hair growth will continue. If there is no improvement in your hair growth after 16 weeks of use, you should discontinue the treatment. The efficacy of the product in clinical trials was not checked beyond 16 weeks.

Consult the doctor or pharmacist with any questions.

### Manner of use:

- **Do not swallow. For external use only.**

- Apply directly to the scalp area only.
- Do not use on parts of the body 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 that the hair and scalp are completely dry before using the foam.
- Take the cap off the canister, turn the canister upside down and press the nozzle to dispense the foam onto your fingers. The required amount should not exceed 1 gram (the volume of half a capful).
- The foam may melt upon contact with warm skin. If your fingers are warm, first rinse them well in cold water. Be sure to dry them thoroughly before use.
- Spread the foam on the scalp with your fingers and rub it in by gently massaging the balding areas.
- Afterwards wash your hands well.
- After using the product: avoid washing your head for approximately two hours. Do not use a hair dryer to hasten the drying of the hair. Do not place your head on a pillow for at least one hour after applying to the scalp. Avoid exposing the hair to the sun.



Remove the cap



Turn the canister over and press the nozzle

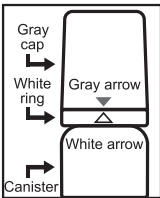


Massage the scalp

### Instructions for opening and closing:

**To open:**

1. Hold the ring (see illustration).
2. While you are holding the ring, turn the cap so that the arrow on the canister is aligned with the arrow on the cap.
3. Take the cap off.



**To close:**

1. Place the cap on the canister and turn until a click is heard.
2. Make sure that the arrows are not aligned, so that the canister will remain protected from opening by children.

### If you have accidentally used a higher dosage

If you have taken an overdose or if a child or someone else has accidentally swallowed the product, proceed immediately to a doctor or a hospital emergency room and bring the package of the product with you.

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

### How can you contribute to the success of the treatment?

Persist with 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 each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of the product, consult the doctor or pharmacist.**

## 4. Side effects

As with any medicine, the use of Hairgain Foam may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Stop using the product and seek medical assistance if you feel:**

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

**Stop the use of this product 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 a feeling of strong heart beats (palpitations)
- Faintness or dizziness
- Swollen hands and feet, shortness of breath
- Sudden and unexplained weight gain
- Persistent local redness or rash

**Very common side effects (appear in more than 1 out of 10 users):**

- Headache

**Common side effects (appear at a frequency of up to 1 out of 10 users):**

- Itching or dermatitis
- Unwanted non-scalp hair growth has been reported (including facial hair growth in women)
- Always be sure to wash your hands thoroughly after using the product. If the foam is accidentally applied to body parts other than the scalp, rinse the area thoroughly with plenty of water.

**Uncommon side effects (appear with a frequency of up to 1 out of 100 users):**

- Nausea

**Rare side effects (appear with a frequency of up to 1 user out of 1,000):**

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

**Additional side effects that can appear and whose frequency is unknown:**

- Depressed mood
- Eye irritation
- Vomiting
- Scalp irritation such as local redness, dryness and flaky skin have been reported. These side effects may be due to the additional ingredients in the product: butylated hydroxytoluene, cetyl alcohol and stearyl alcohol. These side effects are usually temporary, but if they persist, you should stop using the product.
- 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 likely due to a change in the growth cycle and should stop within a few weeks. If the hair loss continues for longer than two weeks, stop using the product and consult the doctor.
- If a change in hair color or texture occurs, stop using the product.

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

### Reporting of 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](http://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 Perrigo via the following address:

[www.perrigo-pharma.co.il](http://www.perrigo-pharma.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 the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and the canister. The expiry date refers to the last day of that month.
- Store below 25°C.
- Warning! Flammable substance, protect from fire.

## 6. Additional Information

- In addition to the active ingredient, the medicine 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 570 mg alcohol per 1 gram of foam.
- How Hairgain Foam looks like and the contents of the package: Hairgain Foam is a creamy white foam packaged in a 60 gram metal canister (spray), in a carton package.
- Registration holder, manufacturer and address: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Revised in December 2020.
- Drug registration number at the National Drug Registry of the Ministry of Health: 151.07.33885

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