

# hairgaine® 5

Minoxidil 5%

50 mg/ml cutaneous solution

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to use Hairgaine 5 carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

### In this leaflet:

1. What Hairgaine 5 is and what it is used for
2. Before you use Hairgaine 5
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### 1. WHAT HAIRGAIN 5 IS AND WHAT IT IS USED FOR

Hairgaine 5 is indicated for cutaneous use, contains a 50 mg/ml concentration of minoxidil in a cutaneous hydroalcoholic solution. Hairgaine 5 is indicated in the treatment of male and female baldness, known as androgenic alopecia, and alopecia areata, also known as spot baldness.

### 2. BEFORE YOU USE HAIRGAIN 5

#### Do not use Hairgaine 5

- If you are allergic (hypersensitive) to minoxidil or to any of the other Hairgaine 5 components;
- If you have scalp psoriasis, seborrheic dermatitis, a sunburn, irritation or abrasion of the scalp you should not use a minoxidil solution;
- If you are under 18 years of age.

#### Take special care with Hairgaine 5

- If you suffer from arterial hypertension or from a heart disease, for example coronary insufficiency;
- If you have hepatic and/or renal function insufficiency; or if you are elderly;
- Minoxidil cutaneous solution applied to the scalp does not cause severe secondary reactions, as absorption is negligible;
- Avoid contact with the eyes, mucosae and areas of damaged skin;
- Wash your hands after applying the medicine.

#### Using Hairgaine 5 with other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should tell your doctor or pharmacist if you are taking minoxidil per os or if you are applying any of the following substances to your scalp: corticoids, vaseline or retinoids.

#### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Hairgaine 5 should not be used by pregnant women or by women who are breast-feeding.

#### Important information about some of the components of Hairgaine 5

Hairgaine 5 contains propylene glycol: may cause skin irritation.

### 3. HOW TO USE HAIRGAIN 5

You should check with your doctor or pharmacist in case of doubts.

Hairgaine 5 is intended for external use and should be applied only to the scalp, twice daily (every 12hrs); when your hair is completely dry.

The dose for each application is 1 ml of solution (corresponding to 30 drops), regardless of the size of the area to be treated. Spread the product from the centre out to the edge of the scalp with your fingers.

The maximum recommended dose is 2 ml and should not be exceeded with the possibility of systemic effects.

If you apply Hairgaine 5 at night you should wait 30 minutes before laying down in order to avoid medicine loss to the pillow.

The treatment period is of approximately one year; the best results are observed at the end of this period. At this point Hairgaine 5 should be used according to clinical assessment.

In order to maintain and to improve the benefits achieved, the administration should continue twice daily after the attack phase.

Experience has shown that the sooner treatment starts, the better the results are because there are more hair follicles capable of responding to the effect of the medicine.

Avoid the contact with the eyes, mucosae and damaged skin area.

Wash your hands after each application.

The cutaneous solution bottle should not be used for other purposes.

#### If you apply more Hairgaine 5 than recommended

Were not observed overdosage cases.

#### If you forget to use Hairgaine 5

In case you have forgotten to apply the solution in the scheduled hour apply it as soon as you remember and after continue as determined before. Do not apply a double dose to make up for a missing dose.

If you have any further questions of how to use this medicine, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Hairgaine 5 can cause side effects, but these are not experienced by all the users.

#### Frequent ( $\geq 1/1000$ , $< 1/10$ ):

The most common adverse reactions are minor dermatological reactions which do not interfere with the treatment continuation but must be reported to your doctor (consult a dermatologist).

- Skin - scalp:
- Itching, dry skin, peeling;
  - Irritation and irritative dermatitis;
  - Burn sensation;
  - Reversible diffuse hypertrichosis (face, eyebrows, ears, arms).

#### Non frequent ( $\geq 1/1000$ , $< 1/100$ ):

- Skin - scalp:
- Eczema, folliculitis, local erythema;
  - Seborrheic dermatitis exacerbation;
  - Allergic contact dermatitis;

Body: - edema (salt and liquids retention);

- Cardiovascular system:
- Palpitation, chest pain, tachycardia;
  - Electrocardiogram alteration (ECG);
  - Cardiac frequency increase;
  - Heart rate increase.

(Note: has not been established a causal relation between the cardiovascular effects and minoxidil topical use).

#### Rare ( $\geq 1/10000$ , $< 1/1000$ ):

- Skin - scalp:
- Allergic contact dermatitis;
  - Baldness, capillary alterations;

Nervous system:

- Cephalgia (headache), weakness, dizziness, vertigo, delusions, anxiety, asthenia.

Reproductive/urinary system:

- Urinary infections, renal calculus;
- Sexual dysfunction.

Eyes:

- Visual disturbance (visual acuity decrease);
- Conjunctivitis.

Ears:

- Buzz sensation;
- External otitis.

(Note: has not been established a causal relation between the effects in the eyes or in the nervous, reproductive and urinary systems and minoxidil topical use).

Signs and symptoms of systemic absorption: chest pain (angina), irregular and accelerated heart rate, hypotension, neuritis, edema, vasodilation.

In case of palpitations, chest pain, dizziness or cephalgia the therapy should be interrupted and a doctor should be consulted.

If any of the referred side effects worsen or in case you experience new ones, not mentioned in this leaflet, inform your doctor or pharmacist.

### 5. HOW TO STORE HAIRGAIN 5

Keep out of the reach and sight of children.

Do not store above 30°C. Keep the bottle tightly closed, in the outer carton, protected from light and moisture.

Do not use Hairgaine 5 after the expiry date which is stated on the label and on the carton after "EXP". The expiry date refers to the last day of the indicated month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer necessary. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

#### What Hairgaine 5 contains

The active substance is minoxidil.

The other components are: isopropyl alcohol, propylene glycol, salicylic acid, 96% ethanol and purified water.

#### What Hairgaine 5 looks like and the contents of the pack

Hairgaine 5 is a clear cutaneous solution, colourless or lightly yellow with an alcoholic odour. It is stored in an 100 mL white bottle of low density polyethylene, with a high density polyethylene dropper applicator and a cap.

Once filled, the bottles are packaged in suitably printed cartons, along with an information leaflet.

Are available one and two bottles packages.

It is possible that not all the packages presentations are commercialized.

#### Marketing Authorisation Holder and Manufacturer

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#### THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by your-self interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Council of Arab Health Minister,  
Union of Arab Pharmacists