

Package leaflet: Information for the user

Regaine® for Men Extra strength Scalp Foam 5% w/w Cutaneous foam minoxidil

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet.
You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if your symptoms worsen or do not improve after 4 months.

What is in this Leaflet

1. What Regaine® Foam is and what it is used for
2. What you need to know before you use Regaine® Foam
3. How to use Regaine® Foam
4. Possible side effects
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1. WHAT REGAINE® FOAM IS AND WHAT IT IS USED FOR

Regaine® Foam contains minoxidil. Minoxidil regrows hair and stabilizes hair loss in men with a receding hairline and crown balding by revitalization of hair follicles.

Regaine® Foam is used to treat men with common hereditary hair loss (also called androgenetic alopecia). It is to be used only on the scalp (head).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE REGAINE® FOAM

Do not use Regaine® Foam if you:

- are allergic to minoxidil or any of the other ingredients of this medicine. (listed in Section 6)

Warnings and precautions

Talk to your doctor or pharmacist before using Regaine® Foam

- If you suffer from heart disease including abnormal heart rhythms or rates, angina or chest pains and/or circulation disorders.
- When minoxidil passes into the blood stream it can cause some side-effects related to low blood pressure such as chest pain, rapid heartbeat, faintness, dizziness, sudden unexplained weight gain or swollen hands and feet. It can also cause persistent redness or irritation of the scalp. If you experience any of these side effects stop using the medicine and tell your doctor.
- Some patients have experienced changes in hair colour and texture with this medicine.
- Increased hair shedding (old hairs fall out as new hairs grow in their place) may occur during the initial 2 to 6 weeks of treatment. This is a sign that it works and that new hairs are replacing old hairs. This stops within a couple of weeks. If shedding persists, stop using Regaine® Foam and consult with your doctor.
- Accidental ingestion may cause serious cardiac adverse events. Therefore this product has to be kept out of the reach of children.
- If the foam is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water to avoid any unwanted hair growth.

You should not use Regaine® Foam if:

- The pattern of your hair loss differs from a receding hair line and crown balding.
- You have no family history of hair loss.
- Your hair loss is sudden and/or patchy.
- You do not know the reason for your hair loss.
- Your scalp is inflamed, infected, irritated or painful.

▲ Regaine® Foam is EXTREMELY FLAMMABLE!

Avoid fire, flame, or smoking during and immediately following application.

Children and adolescents

Regaine® Foam should not be used by children and adolescents below 18 years.

Other medicines and Regaine® Foam

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
- Regaine® Foam should not be used concomitantly with other medications applied topically on the scalp.

Other cosmetic hair products and Regaine® Foam

Use of shampoo during treatment

You should use a mild shampoo in conjunction with using Regaine® Foam. Your scalp must be dry before you apply Regaine® Foam.

Use of hair grooming products during treatment

For best results, Regaine® Foam should be allowed to soak into the scalp before using any styling products. Apply Regaine® Foam first, and then apply your styling products as usual. Do not mix with other preparation for use on the scalp.

Advice about hair colour or perming

There is no available information if these treatments change the effect of Regaine® Foam. However, to avoid possible scalp irritation, you should make sure all of the Regaine® Foam has been washed off the hair and scalp before using these chemicals. Also, you should tell your hair care professional that you are using Regaine® Foam.

Pregnancy and breast feeding and fertility

Regaine® Foam is not for use by women.

This medicine is not recommended during pregnancy, lactation or when trying to conceive.

Driving and using machines

Regaine® may cause dizziness or low blood pressure. If you experience these side-effects do not drive or operate machinery.

Regaine® Foam contains:

- **ethanol (alcohol)** which may cause burning and/or irritation if you get it accidentally in your eye. If you get Regaine® Foam in your eye, mouth or a cut or damaged skin, wash the area well with plenty of cool tap water.
- **Butylated hydroxytoluene** which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
- **Cetyl alcohol** and **stearyl alcohol** which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE REGAINE® FOAM

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

Use this foam twice a day to achieve and maintain the desired effect on hair growth.

This foam is for use on the normal healthy scalp only. It should NOT be used on inflamed, infected, irritated or painful scalp skin. Do NOT apply on other parts of the body.

Make sure to apply the foam directly to the scalp.

Avoid contact with the eyes. If you get the foam in your eyes, rinse your eyes immediately with plenty of cool tap water.

Before using the foam:

Your hair and scalp should be dry.

How to apply the foam:

Apply a dose of 1 g (equivalent to the volume of half a capful) to the hair loss area twice a day.

1. To open the container, match the arrow on the can ring with the arrow on the cap. Remove the cap (Figure 1).

2. The foam may begin to melt on contact with warm skin. If your fingers are warm, rinse them in cold water first. Be sure to dry them thoroughly before handling the foam.

3. Hold the can upside down and press the nozzle to dispense the foam product onto your fingertips (Figure 2). The total amount of foam applied should not be more than 1 g (equivalent to the volume of half a capful).

4. Using your fingers, massage the foam lightly into the affected areas of the scalp (Figure 3) and then wash your hands immediately after applying the foam.

5. After each use, close the container by snapping the cap back on to the can.



figure 1



figure 2



figure 3

Duration of use with Regaine® Foam

It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men you may need to use this product for at least 4 months before you see results.

What to expect while using Regaine® Foam

In the first couple of months, some users may experience increased hair shedding after using this foam for the first time. This can be a sign that Regaine® Foam is working. This temporary increase in hair shedding generally occurs between 2 and 6 weeks after beginning of treatment and then subsides.

If increased shedding continues after 6 weeks, see your doctor.

Hair is usually soft, downy, colourless. After further use, the new hair should be the same colour and thickness as the other hairs on your head. Since hair grows slowly, Regaine® Foam takes time to work.

Results may be seen in 2-4 months with twice a day use.

If there's no hair regrowth after 4 months, then stop using Regaine® Foam.

The amount of hair re-growth is different for each person. This product will not work for all men.

Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again.

If you use more Regaine® Foam than you should

Follow directions for use. Do not use more than 2 g (equivalent to the volume of one capful) in a day, and do not use more than twice a day. Your hair will not regrow any quicker and you will not get any better effect if you use more or if you use it more often. If a child swallows any Regaine® Foam, take him/her to a hospital immediately (with the Regaine® Foam can if possible, as the doctor may like to have some idea of how much the child has swallowed).

If you forget to use Regaine® Foam

Do not worry if you miss one or two applications, just continue to use the product as though you had not missed the dose.

Do not put double the amount on your scalp if you forget an application, as excessive use may cause low blood pressure, fast heartbeat and drowsiness or tiredness.

If you stop using Regaine® Foam

If you stop using the foam, regrown hair may fall out and your scalp will likely return to its former state within 3-4 months.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Regaine® Foam can have side effects, although not everybody gets them.

STOP using the foam and contact a doctor right away if you notice any of the following symptoms - you may need urgent medical treatment.

- Swollen hands or feet (uncommon).
- Swelling of the face, lips or throat which makes it difficult to swallow or breathe. This could be a sign of a severe allergic reaction (frequency not known, cannot be estimated from the available data)
- Persistent redness, rash or irritation of the scalp (not known).
- Faintness or dizziness (uncommon).
- Rapid or irregular heart beat (rare).
- Chest pain (rare).
- Low blood pressure (not known).
- Sudden unexplained weight gain (common).

Other side effects which may occur:

Common (may affect up to 1 in 10 people)

- Headache
- Itching of skin or rash
- Shortness of breath or difficulty in breathing
- Excessive hair growth

Uncommon (may affect up to 1 in 100 people)

- Nausea.

Not known side effect (frequency cannot be estimated from the available data)

- Eye irritation.
- Vomiting.
- Temporary hair loss.
- Change in hair colour and/or texture.
- Application site reactions which may include itching, irritation, pain, rash, swelling, dry skin and redness on the scalp, ears or face, but can sometimes be more severe and include flaking, dermatitis, blistering, bleeding and ulceration.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: <http://www.hpra.ie>
E-mail: medsafety@hpra.ie
You can also report side effects directly in Malta via ADR Reporting at:
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 Regaine® Foam

Keep this medicine out of the sight and reach of children.

Danger extremely flammable aerosol:
Pressurised container: May burst if heated.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Protect from sunlight and keep Can in the outer packaging. Do not expose to temperatures exceeding 50°C.

Do not use this medicine after the expiry date which is stated on the can. The expiry date refers to the last day of that month.

Exposure of the container and contents to naked flame should be avoided during disposal.

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. Content of the pack and other information

What Regaine® Foam contains

- The **active** substance is minoxidil
Each gram cutaneous foam contains 50 mg of minoxidil (5% w/w).
- The **other ingredients** are ethanol anhydrous, purified water, butylhydroxytoluene (E321), lactic acid, citric acid anhydrous, glycerol, cetyl alcohol, stearyl alcohol, polysorbate 60, propane/butane/ isobutene (propellant)

What Regaine® Foam looks like and contents of the pack

This medicinal product is presented as cutaneous foam in a pressurised container with a child-resistant polypropylene overcap. The foam is white to yellowish in colour and unscented. It is presented in a 60 g (equivalent to 73 ml) aerosol can. The can contains enough for 1 month of treatment. Packs contain 1 or 3 cans. Not all pack sizes may be marketed.

Product Authorisation Holder:

Johnson & Johnson (Ireland) Ltd.
Airton Road, Tallaght,
Dublin 24, Ireland

Manufacturer:

Janssen-Cilag
Domaine de Maigremont, 27100,
Val de Reuil, France

This medicinal product is authorised in the Member States of the EEA under the following names:

Finland, Norway, Sweden: Rogaine
Austria, Belgium, Denmark, Ireland,
Iceland, Netherlands, Portugal, Romania,
Slovenia, Spain: Regaine
France: Alostil

**This leaflet was last revised in
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