

Package leaflet:

Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam Minoxidil 5%

- This medicine is used to treat hereditary hair loss in men aged 18-49 years.
- This product is for men only and should **NOT** be used by women.
- DO not apply to other areas of the body other than the scalp. If accidentally applied rinse thoroughly with plenty of water. *see section 2*
- **Follow the instructions on how to use this product carefully.** *See section 3*
- **This medicine is for external use only and should only be applied to your scalp.** *See section 3.*
- **This product is extremely flammable and should be used and disposed of carefully.** See Special Warnings Relating to Regaine Extra Strength Scalp Foam. *See section 2.*

What is in this leaflet

1. What the medicine is for
2. Before using this medicine
3. How to use this medicine
4. Possible side effects
5. Storing this medicine
6. Further Information

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again

1. What the medicine is for

Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam is a medicine used to treat common hereditary hair loss in men aged 18-49 years, by preventing further hair loss and helping hair re-growth. It contains minoxidil, which is thought to work by aiding the blood flow to the hair follicles on your scalp.

- The medicine is only for use in **men** aged between **18 and 49 years**.
- Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam works best in men with hair loss or thinning at the top of the scalp.
- Those who are younger, 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 Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam if you have been bald for many years or have a large area of hair loss.

Hereditary hair loss is recognisable because:

- Of 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.

2. Before using this medicine

Do not use this medicine...

- If you are **female**.
- If you are **under the age of 18 or over the age of 49**.
- If you have had a bad reaction to minoxidil or any of the other ingredients
- If you have hair loss caused by drug treatment
- If you have total baldness or complete loss of all body hair.

- If the cause of your hair loss is unknown or it is sudden and unexpected.
- If you have **high blood pressure**, even if it is not being treated.
- If you have any **condition that affects your scalp**, including sunburn and psoriasis.
- If you have a **shaved scalp**.
- If you are using **creams ointments or lotions** used to treat scalp conditions, e.g.
 - Dithranol- used to treat psoriasis
 - Tretinoin- used to treat acne or other skin disorders
 - Corticosteroids- a type of anti-inflammatory e.g. hydrocortisone, betamethasone dipropionate
- If you have any kind of **dressing or bandage** on your scalp.
- Unless you know that your scalp is **normal and healthy**.

If any of these apply to you **get advice from a doctor or pharmacist before using Regaine®**

Talk to your doctor or pharmacist...

- If you are at all unsure whether your scalp is normal and healthy.
- If you suffer from **heart disease**, including abnormal heart rhythms or rates, angina or chest pains and/or circulation disorders.
- **If you are taking or using any other medicines** including:
 - Certain blood pressure medicines called 'vasodilators' e.g. hydralazine. There is a potential risk that minoxidil, the active ingredient in Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam.
 - may interact with these medicines and increase their effect. If you are not sure about the medicine you are taking or using, show the bottle or pack to your pharmacist.

If any of these bullet points apply, **talk to a doctor or pharmacist**.

If you are pregnant or breast-feeding;

- This product is for men and should **NOT** be used by women. It should **NOT** be used if you are pregnant or breast-feeding.

Some of the ingredients can cause problems

- Regaine Extra Strength Scalp Foam contains ethanol (alcohol), which will cause burning and irritation if you get it in the eye. If you get Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam in your eye, mouth or on a cut or damaged skin, wash the area well with lots of cool tap water.
- Cetyl alcohol or stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
- Butylated hydroxytoluene (E321) may cause local skin reactions (eg contact dermatitis), or irritation to the eyes and mucous membranes.

Special warnings relating to Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam

- If 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, swollen hands and feet or persistent redness. If you experience any of these side-effects, stop using the medicine and tell your doctor.

When Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam is used as recommended, it is extremely unlikely that these effects will occur. However there is a chance the drug could get into the blood stream if it is over used or if there is a scalp condition such as psoriasis present. Therefore it is very important that you use the medicine as recommended and follow the instructions very carefully. *See section 3.*

- The product in this pressurized container, is extremely flammable, therefore exposure of the container or its contents to naked flames should be avoided. Protect from sunlight and do not expose to temperatures above 50°C/122°F. Do not pierce or burn, even after use. Do not spray on a naked

flame or any incandescent material. Keep away from sources of ignition – No smoking. Do not use near, or place container on, polished or painted surfaces.

- Avoid contact with the eyes, mouth, broken skin and sensitive areas, if the foam is accidentally applied to areas of the body other than the scalp rinse thoroughly with plenty of water.
- Do not apply to areas of the body other than the scalp.
- Exceeding the recommended dose will **NOT** re-grow your hair any more quickly and you have an **increased likelihood of getting side-effects**.

3. How to use this medicine

Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam is for topical and external use only. It should only be applied directly to the scalp area.

- Do not apply to areas of the body other than the scalp
- Wash your hands thoroughly before and after apply the foam and rinse other areas that have come into contact with the foam.
- Make sure your hair and scalp are completely dry before applying the foam.
- To open container: Match arrow on can ring with arrow on cap. Pull off cap.
- Hold the can upside down and press nozzle to dispense the foam onto your fingers. The total amount of foam applied should not exceed 1g (equivalent to the volume of half a capful).
- 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.
- The foam should be massaged lightly into the affected areas of the scalp

Daily dose for Adult men

Age Male adults aged 18 to 49 years

Dose

- On a completely dry scalp and hair, apply a dose of 1g (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 2g in a day.
- Do not use more than twice a day.
- This product should **NOT** be used by women.

Continued use of Regaine

- You may need to use this medicine twice daily for at least 8 weeks 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.
- If you have no improvement in your hair growth after 16 weeks of use, you should discontinue treatment.
- Clinical trials on Regaine Foam efficacy have not been carried out beyond 16 weeks.
- If at any time during your treatment you are concerned you should consult your doctor or pharmacist.

If anyone uses too much

- Seek immediate medical advice if anyone, including a child, uses too much of this medicine. Take the medicine container with you.

If you forget to apply a dose of the foam

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.**

If you accidentally swallow the foam

If anyone including a child, swallows any of the foam, take them to a hospital immediately with the Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam pack if possible, as the doctor may like to have some idea of how much they have swallowed.

4. Possible side effects

Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam can have side-effects like all medicines, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using the medicine and seek immediate help:

- Chest pain.

If you experience any of the following, stop using the medicine and tell your doctor:

- Low blood pressure.
- Rapid heart beat.
- Faintness and dizziness.
- Commonly: swollen hands or feet, shortness of breath, high blood pressure.
- Sudden unexplained weight gain.
- Persistent local redness or rash.
- Commonly: Depression.

Other effects which may occur, include

- Very commonly: headache
- Commonly: itching, excessive hair growth, acne, rash, irritated skin, inflammatory skin disorders causing redness and itching, muscle pain, general pain.
- Scalp irritation such as local redness, dryness, flaky skin have all been reported. This may be due to the hydroxybutylated toluene, cetyl alcohol and/or stearyl alcohol in the product. This is usually only a temporary effect, but if it is persistent you should stop using this product.
- Unwanted non-scalp hair has occasionally been reported. Always wash your hands thoroughly after application and if you accidentally apply foam to parts of the body other than the scalp, rinse thoroughly with plenty of water.
- Temporary hair loss may occur during the first 2-6 weeks of use. This is likely to be as a result of a change within the growth cycle and it should stop within a couple of weeks. If this hair loss continues for longer than two weeks, stop using the product and talk to your doctor.
- Change in hair colour and/or texture may occur. If this happens you should stop using Regaine.

If you experience any side-effects not included in this leaflet or are unsure of anything, tell your doctor or pharmacist. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.yellowcard.gov.uk; alternatively you can call freephone 0808 100 3352 (available between 10am – 2pm Monday to Friday) or fill in the paper form available at your pharmacy.

5. Storing the medicine

Keep out of sight and reach of children.

Do not store above 25°C.

Do not use after the expiry date on the base of the can.

The product in this pressurized container, is extremely flammable, therefore exposure of the container or its contents to naked flames or any incandescent material should be avoided.

Protect from sunlight and do not expose to temperatures above 50°C/122°F.

Do not pierce or burn the container, even after use. Do not use while smoking.

Do not use near, or place container on, polished or painted surfaces.

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

6. Further information

What's in this medicine

The active substance in 1g of Regaine is Minoxidil 50mg.

Other ingredients are: Ethanol anhydrous, purified water, butylated hydroxytoluene (E321), lactic acid, citric acid anhydrous, glycerol, cetyl alcohol, stearyl alcohol, polysorbate 60, Propane, butane, isobutane.

What the medicine looks like

Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam is a foam contained in a 73ml (equivalent to 60 g) can, enough for 1 month of treatment. Packs contain 3 cans.

Product License holder:
McNeil Products Ltd,
Maidenhead, Berkshire,
SL6 3UG, UK.

Manufacturer:
Janssen-Cilag
Domaine de Maigremont, 27100,
Val de Reuill, France

This leaflet was prepared July 2014.
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FURTHER INFORMATION ABOUT REGAINE EXTRA STRENGTH SCALP FOAM 5% W/W CUTANEOUS FOAM

Q If my hair growth is restored using Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam, what will the new hair look like?

A If you respond to your treatment, your initial re-growth may at first be soft, downy (“vellus”) hair and may be barely visible.

After further treatment, your hair re-growth may change and become the same colour and thickness as the rest of your hair.

Q Is shampooing necessary before applying Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam?

A No but if you do choose to shampoo, we recommend the use of a shampoo with a gentle cleansing and conditioning action that does not impede the absorption of Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam.

Q Can I use a hair dryer with Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam?

A Yes, but not to dry the foam itself.

Q Can I use common hair styling preparations such as hair gels or hair sprays while using Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam?

A Yes, but Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam should be applied to the dry scalp before these other preparations are applied.

Q Can I have my hair dyed?

A Yes, you may, there is no need to change your hair care routine. However, you should tell your hair care professional that you are using Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam. To minimize breakage of existing hair, just ask that any massaging on your scalp be gentle, and that a comb be widely spaced, round teeth be used to avoid excessive pulling.

Q Can Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam be used with a sun-blocking agent?

A No. if you are planning to be in the sun after applying Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam, use headwear.

Q Can I apply Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam after swimming?

A Yes, as long as hair is dry. However, Regaine Extra Strength Scalp Foam should not be applied more frequently than twice a day.

Q How long will each can of Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam last?

A One can of Regaine Extra Strength Scalp Foam 5% w/w Cutaneous Foam should last for 30 days (one month), if applied twice a day according to directions. As you near the end of a month’s supply, you should plan to re-new it so that you do not miss a daily application.