

EX00466



Regaine[®]

EXTRA STRENGTH

SCALP FOAM

5% W/W CUTANEOUS FOAM

MINOXIDIL



**PATIENT INFORMATION
LEAFLET**



**Danger Extremely
Flammable Aerosol**

McNeil
Pharmaceuticals Ltd.

Regaine®

for MEN

EXTRA STRENGTH

Scalp Foam

5% w/w Minoxidil

Cutaneous Foam

- 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® for Men Extra Strength Scalp Foam. *See section 2 ►*

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Now read all of this leaflet carefully before you start using this medicine because it contains important information for you. Keep the leaflet. You may need to read it again.

1 What the medicine is and what it is used for

Regaine® for Men Extra Strength Scalp 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® for Men Extra Strength Scalp 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® for Men Extra Strength Scalp 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 What you need to know before you use this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X 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 ever 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.
 - Petrolatum – a common ingredient in hair wax or gel.
- 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 bullet points apply to you now or in the past, **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. hydrazaline. There is a potential risk that minoxidil, the active ingredient in Regaine® for Men Extra Strength Scalp 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 now or in the past, **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.



Driving and using machines

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



Some of the ingredients can cause problems

- Regaine® for Men Extra Strength Scalp Foam contains 536.3 mg of alcohol (ethanol) in each 1 g. It may cause burning sensation on damaged skin. Ethanol may cause burning and irritation of the eye.

If you get Regaine® for Men Extra Strength Scalp 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® for Men Extra Strength Scalp 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, persistent redness or irritation of the scalp. If you experience any of these side-effects, stop using the medicine and tell your doctor.

When Regaine® for Men Extra Strength Scalp 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 your medicine as recommended and follow the instructions very carefully. *See section 3* ►

- **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. Do not expose to temperatures exceeding 50°C.
- 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**.
- Cases of excessive hair growth on the body of infants have been reported following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hair growth returned to normal within months when infants were no longer exposed to minoxidil. Care should be taken to ensure that children do not come into contact with areas of your body where you have applied minoxidil topically. Consult a doctor if you notice excessive hair growth on the body of your child during the period you are using topical minoxidil products.

3 How to use this medicine

Regaine® for Men Extra Strength Scalp 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 applying 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 1 g (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.



i 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 1 g (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 g in a day.
- Do not use more than twice a day.
- This product should **NOT** be used by women.

i 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 and 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® for Men Extra Strength Scalp Foam pack if possible, as the doctor may like to have some idea of how much they have swallowed.

4 Possible side-effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

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

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

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

- Allergic reactions including swollen face, skin redness or itching or throat tightness.
- Low blood pressure.
- Fast heart beat or an increased awareness of the heart beat (palpitations).
- Faintness or dizziness.
- Swollen hands or feet, shortness of breath.
- Sudden unexplained weight gain.
- Persistent local redness or rash.

Other effects which may occur, include

Very common (may affect more than 1 in 10 people)

- Headache

Common (may affect up to 1 in 10 people)

- Itching or dermatitis.
- Unwanted non-scalp hair has been reported (including facial hair growth in women). Always wash your hands thoroughly after application and if you accidentally apply the foam to parts of your body other than the scalp, rinse thoroughly with plenty of water.

Uncommon (may affect up to 1 in 100 people).

- Nausea.

Rare (may affect up to 1 in 1,000 people)

- Change in hair texture may occur.
 - If this happens you should stop using Regaine.

Other effects which may occur but it is not known how often:

- Depressed mood.
- Eye irritation.
- Vomiting

- 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.
- Acne-like rash, itchy rash, blistering, bleeding or ulceration.
- 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 2 weeks, stop using the product and talk to your doctor.
- Change in hair colour may occur. If this happens you should stop using Regaine.

If you experience 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store this medicine

Keep out of the sight and reach of children.

Do not store above 25°C.

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

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. Do not expose to temperatures exceeding 50°C. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What this medicine contains

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

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® for Men Extra Strength Scalp Foam is a foam contained in a 73 ml (equivalent to 60 g) can, enough for 1 month of treatment. Packs contain 1 or 3 cans.

Product Licence holder and Manufacturer:

McNeil Products Ltd, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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Regaine® is a registered trade mark.

FURTHER INFORMATION ABOUT

REGAINE® FOR MEN EXTRA STRENGTH SCALP FOAM

Q If my hair growth is restored using Regaine® for Men Extra Strength Scalp Foam, what will the new hair look like?

A If you respond to 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® for Men Extra Strength Scalp 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® for Men Extra Strength Scalp Foam.

Q Can I use a hair dryer with Regaine® for Men Extra Strength Scalp 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® for Men Extra Strength Scalp Foam?

A Yes, but Regaine® for Men Extra Strength Scalp 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® for Men Extra Strength Scalp Foam. To minimize breakage of existing hair, just ask that any massaging of your scalp be gentle, and that a comb with widely spaced, round teeth be used to avoid excessive pulling.

Q Can Regaine® for Men Extra Strength Scalp Foam be used with a sun-blocking agent?

A No. If you are planning to be in the sun after applying Regaine® for Men Extra Strength Scalp Foam, use headwear.

Q Can I apply Regaine® for Men Extra Strength Scalp Foam after swimming?

- A** Yes, as long as hair is dry.
However, Regaine® for Men Extra Strength Scalp Foam should not be applied more frequently than twice a day.
- Q** How long will each can of Regaine® for Men Extra Strength Scalp Foam last?
- A** One can of Regaine® for Men Extra Strength Scalp 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.

