

User Information Leaflet

Regaine for Men Extra Strength 5% w/w cutaneous solution

Minoxidil

For MEN AND WOMEN

- This medicine is used to treat hereditary hair loss in men and women aged 18 – 65 years.
- 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*
- There are 2 different ways you can apply this product, choose the best option for you and 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 flammable and should be used and disposed of carefully. See Special Warnings Relating to Regaine Extra Strength. *See section 2*

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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 is a medicine used to treat common hereditary hair loss in men and women aged 18-65 years, by preventing further hair loss and helping hair regrowth. It contains minoxidil which is thought to work by aiding the blood flow to the cells in your scalp which grow hair.

- The medicine is for use in men and women aged between 18 and 65 years.
- Regaine Extra Strength works best in men and women with hair loss or thinning at the top of the scalp.
- Regaine Extra Strength works best in women who have general thinning over the entire 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 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

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.

Do not use this medicine...

■ If you are under the age of 18 or over the age of 65.

■ If you are hypersensitive (allergic) to minoxidil, ethanol or propylene glycol.

■ If you have high blood pressure (even if it is being treated).

■ If you have known cardiovascular disease or cardiac arrhythmia (abnormal heart rhythms).

- If you have inflamed, infected, irritated or painful scalp skin.
- If you have hair loss due to childbirth.
- If the cause of your hair loss is unknown, or it is sudden and unexpected.
- If you have any condition that affects your scalp, including sunburn and psoriasis.
- If you have a shaved scalp.
- If you are using medications on the scalp including creams, ointments or lotions used to treat scalp conditions.
- 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 without using Regaine.

Talk to your doctor or pharmacist...

- If you are at all unsure whether your scalp is normal and healthy.
- If while using Regaine you experience low blood pressure, chest pain, rapid heart beat, faintness or dizziness, sudden weight gain, swollen hands or feet or persistent redness or irritation of the scalp.
- If you are taking any other medicines, particularly those prescribed by a doctor including:
 - Dithranol – used to treat psoriasis.
 - Tretinoin – used to treat acne or other skin disorders.
 - Bethmethasone dipropionate - a corticosteroid used to treat skin disorders.

If any of these bullet points apply talk to a doctor or pharmacist and stop using Regaine Extra Strength if you have already started.

If you are pregnant or breast-feeding:

- Do not use if you are pregnant or become pregnant or are 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

- This medicine contains 500 mg of propylene glycol in each 1 ml. Propylene glycol may cause skin irritation.

■ This medicine contains 300 mg of alcohol (ethanol) in each 1 ml. It may cause burning sensation on damaged skin. Ethanol may cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin and mucous membranes) the area should be bathed with large amounts of cool tap water.

Special warnings relating to Regaine Extra Strength

■ If minoxidil passes into the bloodstream it can cause some side effects related to low blood pressure such as chest pain, rapid heart beat, faintness, dizziness, sudden unexplained weight gain, swollen hands and feet or persistent redness of the scalp.

■ If you experience any of these side effects, stop using the medicine and tell your doctor. When Regaine Extra Strength 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*

■ Warning Flammable Liquid and Vapour.

Keep away from heat / sparks / open flames / hot surfaces - No smoking.

Avoid exposure of the container and contents to naked flames during use, storage and disposal. Keep container tightly closed. Store in a well ventilated place.



■ Avoid contact with the eyes, mouth, broken skin and sensitive areas. If the solution 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.

Accidental contact

■ Accidental ingestion may cause serious cardiac adverse events. Therefore, this product has to be kept out of the reach of children.

■ Inhalation of the spray mist should be avoided.

■ 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 Extra Strength is for topical and external use only.

It should only be applied directly to the scalp area.

- Avoid breathing in the spray whilst applying to the scalp.
- Do not apply to areas of the body other than the normal healthy scalp. It should not be used on inflamed, infected, irritated or painful scalp skin.
- Wash hands thoroughly before and after applying the solution and rinse other areas that have come into contact with the solution. If the solution is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water to avoid any unwanted hair growth.
- Make sure your hair and scalp are completely dry before applying the solution.
- Choose an appropriate applicator to apply the medicine (see 'Which applicator to use?' below).

Each applicator is designed to accurately release a 1 ml dose when used as described.

Daily dose for Adults:

Age	Dose
Adults aged 18 to 65 years	<ul style="list-style-type: none">■ On a completely dry scalp and hair, apply a 1 ml dose to the total affected area twice daily using the best applicator for you.■ The solution should be massaged lightly into the scalp after application.
<ul style="list-style-type: none">■ Leave at least 12 hours between each use.■ Do not exceed 2 ml in a day.■ Do not use more than twice a day.	

Continued use of Regaine Extra Strength

- You may need to use this medicine twice daily for at least 2 months 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.
- When you stop using this medicine, that hair that has regrown may disappear after 3-4 months and the balding/hair loss process will continue. Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again.
- If you have no improvement in your hair growth after one year of use, you should discontinue treatment.

■ If at any time during your treatment you are concerned you should consult your doctor or pharmacist.

Which applicator to use

The way you apply the solution to your scalp depends on the amount of baldness / thinning you have and the type of applicator you use (see the options and diagrams below). Choose which option is best for you.

Option 1 - Pump spray Applicator

1. This applicator works best for applying the solution to large areas of the scalp.
2. Remove large outer cap and put it to one side; remove smaller inner cap and throw it away.
3. Insert the spray applicator into the bottle and screw on firmly.



4. After aiming the pump toward the centre of the bald area of the scalp, press the pump once and spread the solution with fingertips to cover all the bald area. Repeat a further 5 times. Avoid breathing spray mist. Place outer cap back on bottle when not in use.
5. The total of 6 sprays will deliver the 1 ml dose of minoxidil that is required.
6. Wash your hands and any other areas other than your scalp which may have come in contact with this medicine.

Option 2 - Extended Spray-tip Applicator

1. This applicator works best for applying the solution to small areas of the scalp, or under hair.



2. The pump spray applicator must be on the bottle to use the extended tip applicator. Follow steps 2 and 3 for the pump spray applicator first.

3. Then remove small spray head from top of pump spray applicator; fit the extended spray-tip applicator onto the spray shaft and push down firmly. Remove the small cap on the end of the extended tip and put to one side.
4. After aiming the applicator toward the centre of the bald area of the scalp, press the pump once and spread the solution with fingertips to cover all of the bald area. Repeat a further 5 times. Avoid breathing spray mist. Replace the small cap of extended tip when not in use.
5. The total of 6 sprays will deliver the 1 ml dose of minoxidil that is required.
6. Wash your hands and any other areas other than your scalp which may have come in contact with this medicine.

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 solution

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 as excessive use may cause low blood pressure, fast heartbeat and drowsiness or tiredness.

If you accidentally swallow the solution

If anyone, including a child, swallows any of the solution, take them to a hospital immediately (with Regaine Extra Strength bottle if possible, as the doctor may like to have some idea of how much they have swallowed). Accidental ingestion may cause serious cardiac adverse events.

4 Possible side-effects

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

Contact a doctor right away if you notice any of the following symptoms - you may need urgent medical treatment.

- 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).
- Swollen hands or feet (common).
- 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:

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

- Headache.

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect more than 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, Website www.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 Storing this medicine

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use after the expiry date stated as 'EXP' on the carton and bottle label.

Warning Flammable Liquid and Vapour. Keep away from heat/ sparks/ open flames/ hot surfaces - No smoking.

Avoid exposure of the container and contents to naked flames during use, storage and disposal. Keep container tightly closed. Store in a well ventilated place. 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 protect the environment.

6 Further information

What's in this medicine?

The active substance in 1 ml of Regaine Extra Strength is Minoxidil 50 mg.

Other ingredients are: Ethanol (alcohol), propylene glycol and water.

What the medicine looks like

Regaine Extra Strength is a clear, colourless to light-yellow solution contained in a 60 ml bottle, enough for 1 month of treatment.

Packs contain 1 or 3 bottles with a pump spray applicator and a spray-tip applicator.

The pump spray and extended spray-tip applicators are CE registered components (CE 0120), manufactured by ASM, Aerosol-Service AG, Industriestrasse 11, 4313 Mohlin, Switzerland.

Product Authorisation holder:

JNTL Consumer Health I (Ireland) Ltd. Block 5, High Street, Tallaght, Dublin 24, Ireland.

Manufacturer:

JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised

Regaine is a registered trade mark.

FURTHER INFORMATION ABOUT Regaine EXTRA STRENGTH

Q If my hair growth is restored using Regaine Extra Strength, 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 maybe 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?

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.

Q If I do shampoo, how long must I wait before applying Regaine Extra Strength?

A To be sure the scalp is thoroughly dry, it is recommended that Regaine Extra Strength be applied one hour after shampooing.

Q Can I use a hair dryer with Regaine Extra Strength?

A Yes, but not to dry the solution itself.

Q Can I use common hair styling preparations such as hair gels or hair sprays while using Regaine Extra Strength?

A Yes, but Regaine Extra Strength should be applied to the dry scalp before these other preparations are applied.

Q Can I have my hair dyed or permed?

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. To minimise 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 Extra Strength be used with a sunblocking agent?

A No, if you are planning to be in the sun after applying Regaine Extra Strength use headwear for at least 1 hour until the Regaine has been completely absorbed then apply a sun-blocking agent, remembering to reapply frequently as directed. Do not use Regaine Extra Strength on your scalp if it is red or sunburnt.

Q Can I apply Regaine Extra Strength after swimming?

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

Q How long will each bottle of Regaine Extra Strength last?

A One bottle of Regaine Extra Strength should last for 30 days (one month), if applied twice a day according to directions.

Q Why do boxes always include new applicators?

Why not make refills available?

A Each pack comes with new applicators. So you can be assured that the metering device is always delivering the correct amount of solution and that it has not become clogged or damaged over time.