



C850087

# Regaine®

EXTRA STRENGTH

5% w/v  
Cutaneous  
Solution Minoxidil

for MEN AND WOMEN

USER  
INFORMATION  
LEAFLET

McNeil  
Pharmaceuticals, Inc.

# Regaine<sup>®</sup>

## EXTRA STRENGTH

5% W/V CUTANEOUS SOLUTION

Minoxidil

- 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.

CE 0120

# 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 red, 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.


### **Some of the ingredients can cause problems**

- Propylene glycol may cause skin irritation.
- Regaine Extra Strength contains ethanol (alcohol) which will cause burning and irritation if you get it in the eye. If you get Regaine Extra Strength in your eye, mouth or on a cut or damaged skin, wash the area well with lots 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, 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 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.

### 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 scalp.
- Wash your hands thoroughly before and after applying the solution and rinse other areas that have come into contact with the solution.
- 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.

## **i** Daily dose for Adults:

| <b>Age</b>                        | <b>Dose</b>   |
|-----------------------------------|---|
| <b>Adults aged 18 to 65 years</b> | <ul style="list-style-type: none"><li>■ 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.</li><li>■ The solution should be massaged lightly into the scalp after application.</li></ul> |

- Leave at least 12 hours between each use.
- Do not exceed 2 ml in a day.
- Do not use more than twice a day.

## **i** 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 the medicine, the hair that has regrown may disappear after 3-4 months and the balding / hair loss process will continue.
- 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.

## **i** 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.**

### **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.

**If you experience any of the following side effects, STOP using Regaine and tell your doctor as soon as possible:**

**Common** (may affect up to 1 in 10 people)

- Dyspnoea (shortness of breath) or difficulty breathing.
- Acne.
- Peripheral oedema (swelling).
- Hypertension (high blood pressure).

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

- Hypotension (low blood pressure).

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

- Chest pain.

- Palpitations.
- Increased heart rate.

## Other 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, excessive hair growth, rash, acne, irritated skin, dermatitis, inflammatory skin disorders causing redness and itching, pain, musculoskeletal pain and depression.
- Scalp irritation such as local redness and itching.

**Uncommon** (may affect more than 1 in 100 people)

- 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 and / or texture may occur. If this happens you should stop using Regaine.
- Skin exfoliation (loss of skin), dry skin, rash, irritation and/or rash at site of application.

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

- Red, sore or inflamed skin.

If you experience any side effects not listed in this leaflet, please contact your doctor or pharmacist.

## 5 Storing this medicine

Keep out of the reach and sight 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 cutaneous 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:** McNeil Healthcare (Ireland) Ltd. Airton Road, Tallaght, Dublin 24, Ireland.

**Manufacturer:** Janssen-Cilag  
Domaine de Maigremont, 27100 Val de Reuil, France.

**This leaflet was revised January 2013.**

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 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?

**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 sun-blocking 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 re-apply 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.

