

## **Regaine for Women Regular Strength 2% w/v cutaneous solution Minoxidil**

- This medicine is used to treat hereditary hair loss in women aged 18 – 65 years. It can also be used to treat hereditary hair loss in men 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 for Women Regular Strength. See section 2

### **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 for Women Regular Strength is a medicine used to treat common hereditary hair loss in women aged 18- 65 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. This product can also be used to treat hereditary hair loss in men aged 18 - 65 years.

- The medicine is for use in women aged between 18 and 65 years.
- Regaine for Women Regular Strength works best in women who have general hair thinning of the scalp.
- Those who are younger or have been losing hair for a short period of time are likely to experience the best results.
- You are unlikely to benefit from Regaine for Women Regular Strength if you have been balding / thinning 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 pregnant or breast-feeding.
- 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 are not sure whether your hair loss is hereditary.
- If you have inflamed, infected, irritated or painful scalp.
- If you have total baldness or complete loss of all body hair.
- If the cause of your hair loss is unknown, is due to childbirth or 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 bullet points apply to you now or in the past, get advice from a doctor or pharmacist before using Regaine for Women Regular Strength.

### 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, 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 you are pregnant or breast-feeding:**

- This product 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**

- Propylene glycol may cause skin irritation.
- Regaine for Women Regular Strength contains ethanol (alcohol) which may cause burning and/or irritation if you get it accidentally in your eye. If you get Regaine for Women Regular 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 for Women Regular Strength**

- 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, 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 for Women Regular 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 well-ventilated place. Keep cool.
- 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 for Women Regular 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?'). Each applicator is designed to accurately release a 1 ml dose when used as described.

**Daily dose for Adult Women:**

Age	Dose
Female Adults aged 18 to 65 years	<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>
<ul style="list-style-type: none"> <li>• Leave at least 12 hours between each use.</li> <li>• Do not exceed 2 ml in a day.</li> <li>• Do not use more than twice a day.</li> </ul>	

**Continued use of Regaine**

- You may need to use this medicine twice daily for at least 4 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.
- Once the hair has begun to re-grow, you need to continue using this medicine twice a day for the growth to continue. Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again.
- When you stop using the medicine, the hair that has re-grown may disappear after 3-4 months and the balding / hair loss process will continue.
- If you have no improvement in your hair growth after 8 months 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 following). 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.

## **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 HPRAs Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie).

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 on the bottle label and carton after 'EXP'.

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 well-ventilated place. Keep cool.

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 for Women Regular Strength is Minoxidil 20mg (2% w/v). Other ingredients are ethanol (alcohol), propylene glycol and water. What the medicine looks like Regaine for Women Regular Strength is a clear, colourless to light-yellow solution contained in a 60 ml bottle, enough for 1 month of treatment. Packs contain 1 bottle with a pump spray applicator and a spray-tip applicator.

The pump spray and extended spray-tip applicators are CE registered components (CE 0120). The legal manufacturer is: ASM, Aerosol-Service AG, Industriestrasse 11, 4313 Möhlin, Switzerland.

### **Product Authorisation holder:**

McNeil Healthcare (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

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

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Regaine is a registered trade mark.

## **FURTHER INFORMATION ABOUT REGAINE FOR WOMEN REGULAR STRENGTH**

Q If my hair growth is restored using Regaine for Women Regular 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 for Women Regular 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 for Women Regular Strength.

Q If I do shampoo, how long must I wait before applying Regaine for Women Regular Strength?

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

Q Can I use a hair dryer with Regaine for Women Regular Strength?

A Yes, but not to dry the solution itself.

Q Can I use common hair styling products such as hair gels or hair sprays while using Regaine for Women Regular Strength?

A Most hair gels and hair sprays are ok to use with Regaine for Women Regular Strength. However if they contain petrolatum (petroleum jelly) they should not be used. If you do use hair products with Regaine for Women Regular Strength make sure you apply to a dry scalp before applying any other products.

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 Women Regular 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 for Women Regular Strength be used with a sun-blocking agent?

A No. if you are planning to be in the sun after applying Regaine for Women Regular Strength, use headwear.

Q Can I apply Regaine for Women Regular Strength after swimming?

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



Q How long will each bottle of Regaine for Women Regular Strength last?

A One bottle of Regaine for Women Regular 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.