



EX00464

PATIENT
INFORMATION LEAFLET

Regaine®

FOR WOMEN

REGULAR STRENGTH

Minoxidil 2%
Scalp Solution

CUTANEOUS SOLUTION TO
BE APPLIED TO THE SCALP

TREATS THINNING HAIR

PREVENTS FURTHER HAIR LOSS AND
REGROWS HAIR

McNeil
Pharmaceuticals

Regaine® FOR WOMEN

REGULAR STRENGTH

minoxidil 2% scalp solution

cutaneous solution to be applied to the scalp

- This medicine is used to treat hereditary hair loss in 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 for Women Regular Strength. *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 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.

- 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 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 **pregnant** or **breast-feeding**.
- If you are **under the age of 18 or over the age of 65**.
- If you have ever had a **bad reaction** to minoxidil, ethanol, or propylene glycol.

- If you are not sure whether your hair loss is hereditary.
- 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, is due to childbirth or 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 for Women Regular Strength.**



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 Women Regular Strength, 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 to you now or in the past, **talk to a doctor or pharmacist.**



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 so not drive or operate machinery.



Some of the ingredients can cause problems

- This medicine contains 200 mg of propylene glycol in each 1 ml and may cause skin irritation.

- This medicine contains 561.07 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 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 heart beat, 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 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. 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.
- 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 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 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?'). 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"> ■ 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. |

- 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

- 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. In clinical trials 3 out of every 5 women reported hair re-growth after 8 months of continual use of this product.
- 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 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 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. To open bottle: press down on child resistant cap and turn to unscrew it, as per the instructions engraved on the top of the cap. Remove cap and put it to one side.
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. Remove applicator and place child-resistant-cap back on bottle when not in use. To close the container: screw the cap back into place.
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 the extended tip when not in use. To close the container: remove applicator and screw child resistant cap back in place.
 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 for Women Regular Strength bottle 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 solution 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 propylene glycol 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.
- Changes 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 box.

Warning Flammable Liquid. 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 Contents of the pack and other information

What this medicine contains

The active substance in 1 ml of Regaine for Women Regular Strength is Minoxidil 20 mg.

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

What the medicine looks like

Regaine for Women Regular Strength is a solution contained in a 60 ml bottle, enough for 1 month of treatment. Packs contain 1 bottle, a pump spray applicator and spray-tip applicator.

The pump spray and extended spray-tip applicators are CE registered components.

The legal manufacturer is: ASM, Aerosol-Service AG, Industriestrasse 11, 4313 Möhlin, Switzerland.

Product Licence holder and Manufacturer:

McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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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. As you near the end of a month's supply, you should plan to renew it so that you do not miss a daily application.
- 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.

