

Package leaflet: Information for the user

Regaine for Women Extra Strength Scalp Foam 5% w/w cutaneous foam Minoxidil

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your symptoms worsen or do not improve after 6 months.

In this leaflet:

1. What Regaine for Women is and what it is used for
2. What you need to know before you use Regaine for Women
3. How to use Regaine for Women
4. Possible side effects
5. How to store Regaine for Women
6. Contents of the pack and other information

1. What is Regaine for Women and what it is used for

Regaine for Women contains minoxidil. Minoxidil regrows hair in women by revitalization of hair follicles.

What is female pattern baldness:

- Hair thins on the crown of the scalp. It usually starts with a widening through the parting.
- The front hairline remains unaffected except for normal receding of hair, which happens to everyone as time passes.

Regaine for Women is used to treat women with common hereditary thinning or hair loss in the parting (also called androgenetic alopecia, female type).

2. What you need to know before you use Regaine for Women

Before the start of the treatment with Regaine for Women you should consult a doctor. Hairloss due to disorders of the hormonal system (endocrinological disorders), underlying diseases or malnutrition has to be excluded. In this case you will need a specific treatment.

Do NOT use Regaine for Women if you:

- are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or your pharmacist before using Regaine for Women if you

- Suffer from heart disease including abnormal heart rhythms or rates, angina or chest pains and/or circulation disorders or hypertension.

Regaine for Women is to be used only on the scalp.

Some patients have experienced changes in hair colour and texture with this medicine. Increased hair shedding (old hairs fall out as new hairs grow in their place) may occur during the initial 2 – 6 weeks of treatment. This is a sign that it is working and that new hairs are replacing old hairs. If shedding persists, stop using Regaine for Women and consult with your doctor.

When treatment with minoxidil is stopped, shedding of the hairs will occur again.

Accidental ingestion may cause serious effects to your heart. Therefore this product has to be kept out of the reach of children.

If the foam is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water to avoid any unwanted hair growth.

You should not use Regaine for Women if

- the pattern of your hair loss differs from hair thinning mainly on the top and crown of the scalp
- you have no family history of gradual thinning or gradual hair loss
- your hair loss is sudden and/or patchy
- your hair loss is due to childbirth
- you do not know the reason for your hair loss
- your scalp is red, inflamed, irritated or painful.

Regaine for Women is an EXTREMELY FLAMMABLE AEROSOL!

Avoid fire, flame, or smoking during and immediately following application.

Children and adolescents

Regaine for Women should not be used by children and adolescents below 18 years of age.

Other medicines and Regaine for Women

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Regaine for Women should not be used at the same time with other medications applied topically on the scalp.

Other cosmetic hair products and Regaine for Women

Use of shampoo during treatment

You should use a mild shampoo in conjunction with using Regaine for Women. Your scalp must be dry before you apply Regaine for Women.

Use of hair grooming products during treatment

For best results, Regaine for Women should be allowed to soak into the scalp before using any styling products. Apply Regaine for Women first, and then apply your styling products as usual. Do not mix with any other preparation for use on the scalp.

Advice about hair colour or perming

There is no available information about whether these treatments change the effect of Regaine for Women. However, to avoid possible scalp irritation, you should make sure all of the Regaine for Women has been washed off the hair and scalp before using these chemicals. Also, you should tell your hair care professional that you are using Regaine for Women.

Pregnancy, breastfeeding and fertility

This medicine is not recommended during pregnancy, lactation or when trying to conceive.

Driving and using machines

Regaine for Women may cause dizziness or hypotension. If affected do not drive or operate machinery.

You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines. Descriptions of these effects can be found in other sections.

Read all the information in this leaflet for guidance.

Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

Regaine for Women contains:

Ethanol (alcohol) which will cause burning and irritation if you get it in your eye. If you get Regaine for Women in your eye, mouth or a cut or damaged skin, wash the area well with plenty of cool tap water.

Butylated hydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Cetyl alcohol and **stearyl alcohol** which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Regaine for Women

Always use Regaine for Women exactly as stated in this package leaflet or as your doctor or your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Use this foam once a day to achieve and maintain the desired effect on hair growth.

This foam is for use on the scalp only. Do NOT apply on other parts of the body.

Make sure to apply the foam directly to the scalp.

Avoid contact with the eyes. If you get the foam in your eyes, rinse your eyes immediately with plenty of cool tap water.

Before using the foam:

Your hair and scalp should be dry.

How to apply the foam:

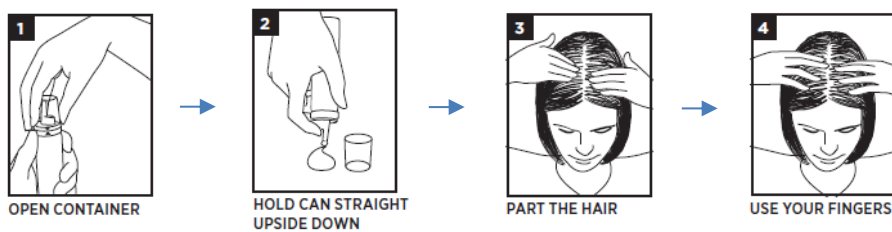
Apply a dose of 1 g (equivalent to the volume of half a capful) to the hair loss area once a day.

To open the container, match the arrow on the can ring with the arrow on the cap. Remove the cap (Figure 1).

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.

Hold the can upside down and press the nozzle to dispense the foam product onto a non-absorbent surface like a clean dish or saucer. The total amount of foam applied should not be more than 1g (equivalent to the volume of half a capful). (Figure 2)

Within your hair thinning areas, make a centre part to help maximize scalp exposure. (Figure 3)
Using your fingertips, spread just enough foam over the hair loss areas and gently massage the foam into the scalp starting from the back to front (forehead) direction. (Figure 4)



Part your hair at least 2 more times on each side of the centre part, and apply the remaining foam to each part as instructed above. Use until all the foam is gone and then wash your hands and the dish or saucer immediately after applying the foam to avoid accidental contact with eyes and mucous membranes.

After each use, close the container by snapping the cap back onto the can and be sure that arrows do not line up so cap remains child resistant.

Duration of use with Regaine for Women

It takes time to regrow hair. Results may occur at 3 months with once a day usage. The maximum hair count was seen after 3 and 6 months of treatment. Further treatment did not increase the hair count. Nevertheless, continued treatment is important to maintain the effect.
Stop using Regaine for Women if there is no hair regrowth after 6 months

What to expect while using Regaine for Women

In the first two to six weeks, some users may experience increased hair shedding after using this foam for the first time.

Hair is usually soft, downy and colourless. After further use, the new hair should be the same colour and thickness as the other hairs on your head. Since hair grows slowly, Regaine for Women takes time to work.

The amount of hair re-growth is different for each person. This product will not work for all women. At present clinical data are available for 12 months treatment with the product.

Special populations

There are no specific recommendations for use in elderly patients or in patients with renal or hepatic impairment.

Pediatric population

Regaine for Women is not recommended for use in adolescents or children below the age of 18 years due to lack of data on safety and efficacy.

If you use more Regaine for Women than you should

Follow directions for use. Do not use more than 1 g (equivalent to the volume of half a capful) in a day, and do not use more than once a day. Your hair will not regrow any quicker and you will not get any better effect if you use more or if you use it more often.

If a child swallows any Regaine for Women, take him/her to a hospital immediately (with the Regaine for Women can if possible, as the doctor may like to have some idea of how much the child has swallowed).

If you forget to use Regaine for Women

Do not worry if you miss one or two applications, just continue to use the product as though you had not missed the dose. Do not put double the amount on your scalp if you forget an application.

If you stop using Regaine for Women

If you stop using the foam, regrown hair may fall out and your scalp will likely return to its former state within 3-4 months.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Regaine for Women can have side effects, although not everybody gets them. The following data on side effects (greater than one treatment-related event and frequency greater than 1% of subjects overall and greater than placebo) are available:

Stop taking Regaine for Women and 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); general itching;
- general skin rash;
- feeling of tightness in the throat.

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:

- weight gain
- increased facial hair growth
- itching, redness and rash
- shortness of breath
- swelling of arms and legs
- high blood pressure
- stinging/burning, itching, dryness/scaling and inflammation of hair follicles at the scalp

Uncommon: may affect up to 1 in 100 people:

- dizziness
- nausea

Rare: may affect up to 1 in 1000 people

- Pain in the chest region

Not known: frequency cannot be estimated from the available data:

- contact allergy
- eye irritation
- accelerated heartbeat, palpitations, low blood pressure
- vomiting
- symptoms at the administration site, which may also affect the ears and the face, such as itching, skin irritations, pain, skin redness, swelling, dry skin and inflammatory skin rash and even exfoliation, skin inflammation (dermatitis), blistering, bleeding and ulceration
- temporary hair loss, changes in hair colour, change in hair texture

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Regaine for Women

Keep this medicine out of the sight and reach of children.

Do not use Regaine for Women after the expiry date which is stated on the base of the can after the letters EXP. The expiry date refers to the last day of that month.

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. Keep the can in the outer carton in order to protect from sunlight. Do not expose to temperatures exceeding 50°C.

Exposure of the container and contents to naked flame should be avoided during disposal. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Regaine for Women contains

The **active** substance is minoxidil

Each gram of cutaneous foam contains 50 mg of Minoxidil (5 % w/w).

The **other ingredients** are ethanol anhydrous, purified water, butylhydroxytoluene (E321), lactic acid, citric acid anhydrous, glycerol, cetyl alcohol, stearyl alcohol, polysorbate 60 and propane/ butane/ isobutane (propellant)

What Regaine for Women looks like and contents of the pack

This medicinal product is presented as cutaneous foam in a pressurised container with a child-resistant polypropylene overcap. The foam is white to yellowish in colour and unscented. It is presented in a 60 g (equivalent to 73 ml) aerosol can. The can contains enough foam for 2 months of treatment. Packs contain 1 or 2 cans.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Johnson & Johnson (Ireland) Ltd.
Airton Road, Tallaght
Dublin 24, Ireland

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden	Roquinna
Austria	Regaine Frauen Schaum
Belgium	Regaine 5% schuim voor cutaan gebruik, vrouwen
Bulgaria	Регайн пiana ze жени 50 mg/g разтвор за кожа
Cyprus	Regaine Women's foam, cut. foam 5%
Germany	Regaine Frauen Schaum
Greece	Regaine Women's foam, cut. foam 5%
Spain	Regaine 50mg/g espuma cutánea para mujer
France	Minoxidil Johnson & Johnson 5% mousse pour application cutanée
Croatia	Regaine Femina 50 mg/g pjena za kožu
Ireland	Regaine for Women Extra Strength Scalp Foam 5% w/w Cutaneous Foam
Romania	Regaine Femina 50 mg/g spuma cutanata
Slovenia	Regaine za ženske 50mg/g dermalna pen

This leaflet was last revised in January 2019