

Package leaflet: Information for the user

Roquinna 50 mg/g 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.

What is in this leaflet:

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

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

Roquinna 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.

Roquinna 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 Roquinna

Before the start of the treatment with Roquinna 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 Roquinna 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 Roquinna if you

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

Roquinna 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 Roquinna and consult with your doctor.

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

If symptoms persist or get worse, or if new symptoms occur, stop use and consult a physician.

Accidental contact

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.

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.

You should not use Roquinna 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.

Roquinna is an EXTREMELY FLAMMABLE AEROSOL!

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

Children and adolescents

Roquinna should not be used by children and adolescents below 18 years of age.

Other medicines and Roquinna

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Roquinna should not be used at the same time with other medications applied topically on the scalp.

Other cosmetic hair products and Roquinna

Use of shampoo during treatment

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

Use of hair grooming products during treatment

For best results, Roquinna should be allowed to soak into the scalp before using any styling products. Apply Roquinna 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 Roquinna.

However, to avoid possible scalp irritation, you should make sure all of the Roquinna has been washed off the hair and scalp before using these chemicals. Also, you should tell your hair care professional that you are using Roquinna.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

Roquinna 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.

Roquinna contains ethanol, butylhydroxytoluene, stearyl alcohol, cetyl alcohol and polysorbate 60

This medicine contains 564.6 mg alcohol (ethanol) in each dose (1 g) of cutaneous foam which is equivalent to 564.6 mg/g (56.46% w/w). It may cause burning sensation on damaged skin. If you get Roquinna 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).

Polysorbates can cause allergic reactions.

3. How to use Roquinna

Always use Roquinna 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.

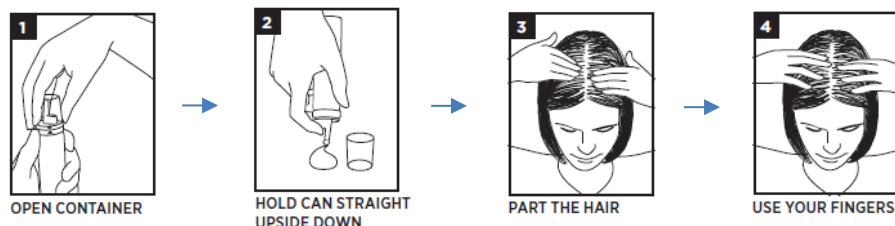
To open the container, match the arrow on the can ring with the arrow on the cap. Remove the cap (Figure 1).

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 Roquinna

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 Roquinna if there is no hair regrowth after 6 months

What to expect while using Roquinna

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, Roquinna 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

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

If you forget to use Roquinna

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 Roquinna

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, Roquinna 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 Roquinna 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Roquinna

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

.Do not use this medicine after the expiry date which is stated on the carton and base of the can after 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 Roquinna 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 Roquinna looks like and contents of the pack

This medicine 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

[To be completed nationally]

For any information about this medicine, please contact [the local representative] of the Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden: Roquinna

Austria: Regaine Frauen

Croatia, Romania: Regaine Femina

Bulgaria: Regaine Foam for Women

Ireland, Slovenia: Regaine for Women

Greece, Cyprus: Regaine Women's Foam

This leaflet was last revised in

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[To be completed nationally – if QR code is used]

< QR Code >

<Detailed and updated information on this product is available by scanning the QR Code included in the
<PIL> <outer carton> with a smartphone. The same information is also available on the following URL:
[URL to be included] <and the <NCA> website>>