



Consumer Medicine Information

This booklet has been written to answer some common questions about REGAINE®, but it does not contain all the information available. If you have any concerns, you should talk to your doctor or pharmacist. This booklet does not take the place of talking to your doctor or pharmacist.

Read this booklet carefully before you start to use REGAINE®. Keep the booklet because you may want to read it again.

What is REGAINE®?

REGAINE® is a solution that is to be used only on your scalp. It contains the active ingredient minoxidil in a mixture of alcohol, propylene glycol and water.

What REGAINE® is used for and how it works

REGAINE® is used for the treatment of hair loss in man and woman. REGAINE® stimulates hair growth and stabilizes hair loss in patients experiencing hair loss or hair thinning.

How effective is REGAINE® in regrowing hair?

It is important for you to understand that REGAINE® does not work well in all people, and how well it works depends on a number of things. Your pharmacist or doctor can best decide whether you are likely to respond to treatment with REGAINE®. You should discuss what results you might expect from treatment with REGAINE® with your pharmacist or doctor.

You may experience a temporary increase in hair shedding in the first 2 – 6 weeks of treatment.

If you respond to treatment with REGAINE®, your initial regrowth may at first be soft, downy hair (“vellus”), and may hardly be visible. After further treatment it is likely that your hair regrowth will change and become the same colour and thickness as the rest of your hair.

Patients using REGAINE® have reported that the loss of hair is slowed during treatment.

Treatment with REGAINE® is a long-term therapy for hair regrowth. If you respond to treatment, you will need to continue to use REGAINE® in order to keep the new hair and also to stop additional hair loss. If you stop using REGAINE® you will probably lose the hair that has already grown back. This hair loss will occur about three to four months after stopping treatment. The balding process will also start again.

Do not use REGAINE® if:

- You do not have a family history of hair loss.
- Your hair loss is patchy and/or sudden, or if the reason for the hair loss is unknown.
- The hair loss is due to childbirth.
- Your scalp is red, inflamed, irritated, infected or painful.
- You have had an allergic reaction to REGAINE® or any of its ingredients.
- You are currently using any topical medications on the scalp.
- You are under 18 or over 65 years of age.
- The expiry date (EXP) printed on the pack has passed.
- You are pregnant or breastfeeding.

What should I tell my pharmacist or doctor before using REGAINE®

Tell your pharmacist or doctor about medical problems you have now or have had in the past. In particular, tell your pharmacist or doctor if:

- You are taking any other medicines, including medicines you have bought without a prescription from a pharmacy or a supermarket.
- You have any heart problems.

Some medicines may affect the way others work. Your pharmacist or doctor will be able to tell you what to do when using REGAINE® with other medicines.

Can REGAINE® be used by children or people over 65 years of age?

As there is no experience with the use of REGAINE® in children or people over 65 years of age, it should not be used by them.

Can I use REGAINE® while I am taking other medicines?

Do not use REGAINE® concurrently with any other medicines on the scalp. Topical corticosteroids, tretinoin or anthralin can alter permeability of the skin and can result in a change in the absorption of minoxidil.

Theoretically, some people taking certain drugs to treat high blood pressure could experience a fall in blood pressure on standing. If you have any concerns please speak to your pharmacist or doctor.

Your treatment with REGAINE® may not be as effective if you take diethyl-carbamazine or paracetamol regularly.

While you are using REGAINE®

- If you are going to have any laboratory tests (e.g. blood or urine), tell your doctor that you are using REGAINE®. It is also important to tell your doctor that you are using REGAINE® if your doctor is going to prescribe for you another type of medicine to take at the same time as using REGAINE®.
- If after 6 months of using REGAINE® no hair growth is seen, you should talk to your pharmacist or doctor about stopping the treatment as any gain from continued treatment is likely to be small.
- Do not change your dose of REGAINE® or stop using REGAINE® without first asking your pharmacist or doctor for advice.
- Do not use REGAINE® more than two times a day, and do not use more solution than your pharmacist or doctor tells you to.
- REGAINE® is for external use only. Never take REGAINE® orally to help hair growth. This could lead to serious side effects.
- Do not apply REGAINE® to any area of the body other than the scalp.
- The use of REGAINE® may cause dizziness or hypotension. If affected, do not drive or operate machinery.
- It is not necessary to shampoo before applying REGAINE®, however if you do wash your hair wait until your hair is absolutely dry before using REGAINE® as it must be applied to a dry scalp. A hair dryer may be used to dry your hair after you have washed it, but do not use it to dry the REGAINE® solution. As REGAINE® needs to be in contact with your scalp for at least four hours at a time, do not wash or wet your scalp for at least four hours after use.

- Avoid contact with the eyes and irritated skin. If there is accidental contact of REGAINE® to your eyes, mouth, nose, ears, or broken or irritated skin, bathe the area with large amounts of cool tap water.
- Use of REGAINE® in conjunction with other products should be discussed with your pharmacist or doctor.

Common questions about using REGAINE®

- Hair sprays and other common hair products can be used while using REGAINE®, however REGAINE® should be applied to the clean, dry scalp before the other products are used.
- Your hair can continue to be dyed or permed. However, tell your hair-dresser/barber that you are using REGAINE®. It may be best to stop using REGAINE® for 24 hours before having your hair dyed or permed to avoid the possibility of any chemical interactions.
- Sunscreens should be applied four hours after the application of REGAINE® to ensure that the sunscreen does not interfere with the effectiveness of REGAINE®. If it is not possible, the sunscreen should be applied no sooner than two hours after application.
For your second daily application, the sunscreen should be shampooed off the scalp. If your scalp gets sunburnt, do not apply REGAINE® until the burn has healed.
A hat may be worn as an alternative to using a sunscreen. Make sure you wait at least one hour after using REGAINE® before wearing your hat.
- You can use REGAINE® after swimming as long as your scalp is dry.
- REGAINE® Topical Application is clear and colourless, however its colour may vary and occasionally have a yellow appearance. The colour of the solution will not affect its effectiveness, nor should it cause staining of clothes or skin. The solution will have no colour when it has dried on the scalp.

How and when to use REGAINE®

- REGAINE® must only be applied when the hair and scalp are completely dry.
- You should continue to use REGAINE® as directed by your pharmacist or doctor. Once REGAINE® is stopped, the appearance of your hair will return to how it was before you started to use REGAINE®.

Directions For Use:

For topical use only. The hair and scalp should be thoroughly dry prior to topical application.

Apply one dose (1 mL) of REGAINE® to the hair loss area of your scalp two times a day, preferably morning and night.

Massage the solution lightly into your scalp, and wash your hands well afterwards. Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp. This dose should be used no matter what the size of the bald spot is. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

It has been shown that twice daily use of REGAINE® may be required for at least four months before you will see the evidence of cosmetically acceptable hair growth.

Response to treatment with REGAINE® may vary widely, and some patients may see faster results than others. Make sure the scalp is dry and that the skin is healthy and intact.

The method of application varies according to the disposable applicator used, as indicated below.

A. PUMP SPRAY APPLICATOR

1. This applicator works best for applying REGAINE® to large areas of the scalp.
2. Remove large outer cap; remove small inner cap and discard it.
3. Insert the pump spray applicator into bottle and screw on firmly.
4. After aiming the pump toward the center of the bald area of the scalp, press the pump once and spread REGAINE® with fingertips to cover all of the bald area.

Repeat for a total of 6 times, to apply a dose of 1 ml of solution. Avoid breathing spray mist. Place large outer cap on bottle when not in use.

B. EXTENDED SPRAY-TIP APPLICATOR

1. This applicator works best for applying REGAINE® 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 A.2 and A.3.
3. 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.
4. After aiming the applicator toward the center of the bald area of the scalp, press the pump once and spread REGAINE® with fingertips to cover all of the bald area. Repeat for a total of 6 times, to apply a dose of 1 ml of solution. Avoid breathing spray mist. If desired, replace the small cap on end of extended tip when not in use.

What if I forget to use REGAINE®

If you forget to use REGAINE® once or twice, just start your twice daily application again and return to your usual schedule.

Do not apply more than 1 ml of REGAINE® and do not use more than twice daily to make up for the dose you missed.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using REGAINE®.

It is important to remember that this list does not include every unwanted effect that has been reported with REGAINE®.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

A) Side effects identified from Clinical Trial Data:

Very common: headache

Common:

- Swelling or puffiness of hands, face, ankles or stomach
- Difficult or labored breathing
- Inflammation of the skin
- Dermatitis acneiform
- Excessive hair growth
- Itching
- Rash

B) Side effects identified during Post-marketing experience with Minoxidil, with frequency category estimated from Spontaneous Reporting Rates:

Very rare:

- Angioedema (the manifestations of angioedema may include the following: lip oedema, oedema mouth, oropharyngeal swelling, pharyngeal oedema, and tongue oedema)
- Hypersensitivity (the manifestations of hypersensitivity reactions may include the following: face oedema, generalized erythema, pruritus generalized, and throat tightness)
- Contact dermatitis
- Dizziness
- Depressed mood
- Eye irritation
- Tachycardia
- Palpitations
- Low blood pressure
- Nausea
- Vomiting
- Application site reactions (these sometimes involve nearby structures like the ears and face and typically consist of itching, irritation, pain, rash, oedema, dry skin and erythema but can sometimes be more severe and include peeling, dermatitis, blistering, bleeding and ulceration)
- Alopecia
- Changes to hair color
- Abnormal hair texture
- Chest pain

Stop use and tell your pharmacist or doctor as soon as possible if you do not feel well while you are using REGAINE®, or if you experience any of the following:

- Low blood pressure
- Chest pain
- Rapid heartbeat

- Faintness or dizziness
- Sudden unexplained weight gain
- Swollen hands or feet
- Persistent redness or irritation of the scalp

If any of the following occur, stop using REGAINE® and tell your doctor immediately or go to casualty at your nearest hospital:

- Pain in the chest, arm or shoulder.
- Signs of severe indigestion.

What to do if REGAINE® is accidentally swallowed

Accidental ingestion may cause serious heart problems. Therefore keep this product out of reach of children.

If REGAINE® is accidentally swallowed, contact your nearest hospital. Some of the symptoms which you may experience are fast heart rate, low blood pressure (lightheadedness or fainting), lethargy, swelling or puffiness of the body.

How to store REGAINE®

- Store at controlled room temperature 20 – 25°C.
REGAINE® is very flammable, and must be kept away from heat, sparks and naked flames. Never use REGAINE® while you are smoking.
- Do not leave REGAINE® in the car, or in the sun on hot days. Too much heat can destroy the product.
- Keep REGAINE® in a place where children cannot reach it, such as in a medicine cupboard. If swallowed, get medical help right away.
- The expiry date is printed on the bottle. Do not use REGAINE® after this date has passed.
- Return any unused solution to your pharmacist.

Description

REGAINE® Topical Application is available as:

- 2% solution containing 20mg minoxidil per mL
- 5% solution containing 50mg minoxidil per mL

Where should I go for further information?

This is not all the information that is available on REGAINE®. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

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Product Registrant

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