

ROGAINE® FOR MEN REGULAR STRENGTH HEREDITARY HAIR LOSS TREATMENT

Consumer Medicine Information

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

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

It is important to remember that ROGAINE® Regular Strength is a PHARMACY MEDICINE.

What is ROGAINE®?

ROGAINE® 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 ROGAINE® is used for & how it works

ROGAINE® is used as a long-term treatment for common baldness. ROGAINE® is not a cure for baldness, but in some men and women it can improve hair regrowth. However, exactly how ROGAINE® works is not known.

How effective is ROGAINE® in regrowing hair?

It is important for you to understand that ROGAINE® 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 ROGAINE®. You should discuss what results you might expect from treatment with ROGAINE® with your pharmacist or doctor.

If you respond to treatment with ROGAINE®, 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 ROGAINE® have reported that the loss of hair is slowed during treatment.

Treatment with ROGAINE® is a long-term therapy for hair regrowth. If you respond to treatment, you will need to continue to use ROGAINE® in order to keep the new hair and also to stop additional hair loss. If you stop using ROGAINE® 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 ROGAINE if:

- You do not have a family history of hair loss.
- Your hair loss is sudden and/or unexplained.
- Your scalp is red, inflamed, irritated, infected or painful.
- You have had an allergic reaction to ROGAINE® or any of its ingredients.
- You are under 18 or over 65 years of age.
- The expiry date (EXP) printed on the pack has passed.
- You are a woman who is pregnant or breast-feeding

What should I tell my pharmacist or doctor before using ROGAINE®?

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 ROGAINE® with other medicines.

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

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

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

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 ROGAINE® may not be as effective, if you take diethylcarbamazine or paracetamol regularly.

While you are using ROGAINE®

- If you are going to have any laboratory tests (e.g. blood or urine), tell your doctor that you are using ROGAINE®. It is also important to tell your doctor that you are using ROGAINE® if your doctor is going to prescribe for you another type of medicine to take at the same time as using ROGAINE®.
- If after 6 months of using ROGAINE® 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 ROGAINE® or stop using ROGAINE® without first asking your pharmacist or doctor for advice.

- Do not use ROGAINE® more than two times a day, and do not use more solution than your pharmacist or doctor tells you to.
- ROGAINE® is for external use only. Never take ROGAINE® orally to help hair growth. This could lead to serious side effects.
- Do not apply ROGAINE® to any area of the body other than the scalp.
- It is not necessary to shampoo before applying ROGAINE®, however if you do wash your hair wait until your hair is absolutely dry before using ROGAINE® 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 ROGAINE® solution. As ROGAINE® 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 ROGAINE® to your eyes, mouth, nose, ears, or broken or irritated skin, bathe the area with large amounts of cool tap water.
- Use of ROGAINE® in conjunction with other products should be discussed with your pharmacist or doctor.
- Your hair can continue to be dyed or permed. However, tell your hairdresser/barber that you are using ROGAINE®. It may be best to stop using ROGAINE® 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 ROGAINE® to ensure that the sunscreen does not interfere with the effectiveness of ROGAINE®. 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 ROGAINE® 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 ROGAINE® before wearing your hat.
- You can use ROGAINE® after swimming as long as your scalp is dry.
- ROGAINE® 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.

Common questions about using ROGAINE®

- Hair sprays and other common hair products can be used while using ROGAINE®, however ROGAINE® should be applied to the clean, dry scalp before the other products are used.

How and when to use ROGAINE®

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

Directions For Use:

Apply one dose (1 mL) of ROGAINE® 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. This dose should be used no matter what the size of the bald spot is. It has been shown that twice daily use of ROGAINE® may be required for at least four months before you will see the evidence of cosmetically acceptable hair growth. Response to treatment with ROGAINE® 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.

How to use the dropper:

1. Remove the large outer cap off the bottle; unscrew the child resistant cap.
2. Hold the bottle upright. While making sure that the dropper is immersed in the solution, squeeze the bulb to fill the dropper to the black line. The applicator now contains one full dose (1 mL) of ROGAINE® and is ready for use.
3. Aim the dropper to the area of the scalp you wish to treat, lifting any hair out of the way with your fingers or comb. Gently squeeze the dropper bulb and apply the solution dropwise. Massage the solution into the scalp gently with your fingers. Wash your hands after you have finished massaging the solution into your scalp. Replace the child-resistant dropper by screwing the dropper firmly onto the bottle. Place the larger outer cap on the bottle when not in use.

What if I forget to use ROGAINE®?

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

Do not apply more than 1 mL of ROGAINE® 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 ROGAINE®.

If you get any side effects, do not stop using ROGAINE® without first talking to your pharmacist or doctor.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you have.

It is important to remember that this list does not include every unwanted effect that has been reported with ROGAINE®. This list includes the unwanted effects that are the most serious or the most common:

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

- allergic-type reactions
- itching and other skin irritations of the treated area of the scalp.
- eczema
- redness of the scalp where ROGAINE® is being applied
- dry skin/scalp flaking
- ROGAINE® contains alcohol which could cause burning or irritation to the eyes, mouth, nose and ears, or sensitive skin areas.
- excessive hair growth on other parts of the body

- increased hair loss

These are the more common side effects of ROGAINE®. For the most part these have been mild.

Tell your pharmacist or doctor as soon as possible if you notice any of the following:

- rapid heart rate
- unexplained rapid weight gain of 2 to 3 kg or more
- swelling or puffiness of hands, face, ankles, or stomach
- dizziness, lightheadedness, or fainting
- problems with vision

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- pain in the chest, arm or shoulder
- signs of severe indigestion.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

What to do if ROGAINE® is accidentally swallowed

If ROGAINE® is accidentally swallowed contact your nearest hospital or Poisons Information Centre (telephone number 13 11 26) immediately. Some of the symptoms which you may experience are fast heart rate, low blood pressure (lightheadedness or fainting), swelling or puffiness of the body.

How to store ROGAINE®

- Keep the Topical Application in a cool place where the temperature stays below 30° C
- ROGAINE® is very flammable, and must be kept away from heat, sparks and naked flames. Never use ROGAINE® while you are smoking.
- Do not leave ROGAINE® in the car, or in the sun on hot days. Too much heat can destroy the product.
- Keep ROGAINE® in a place where children cannot reach it, such as in a medicine cupboard.
- The expiry date is printed on the bottle. Do not use ROGAINE® after this date has passed.
- Return any unused solution to your pharmacist.

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Description

ROGAINE® Topical Application is available as:

- 2% solution containing 20 mg minoxidil per mL. The identification number for ROGAINE Topical Application 2% is AUST R 79911.
- 5% solution containing 50 mg minoxidil per mL. The identification number for ROGAINE Extra Strength Topical Application is AUST R 79914.

Where should I go for further information?

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

Who supplies your medicine

ROGAINE® is supplied by: