

MEN'S Regaine EXTRA STRENGTH FOAM

MINOXIDIL 5% W/W TOPICAL FOAM

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 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 REGAINE®. Keep the booklet because you may want to read it again.

It is important to remember that MEN'S REGAINE® EXTRA STRENGTH FOAM is a PHARMACY MEDICINE.

What is REGAINE®?

REGAINE® is a foam that is to be used only on your scalp. It contains the active ingredient minoxidil in a foam base of alcohol, water, glycerol, cetyl alcohol, citric acid, lactic acid, stearyl alcohol, polysorbate 60, butyl hydroxytoluene and propellant.

What REGAINE® is used for & how it works

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

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.

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 unexplained.
- Your scalp is red, inflamed, irritated, infected or painful.
- You have had an allergic reaction to REGAINE® or any of its ingredients.

- You use other medicines 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 a woman who is pregnant, intending to become pregnant or breast-feeding.

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 such as heart failure or disorders of heart rhythm
- you have blood pressure problems
- you have any skin diseases
- You have had a stroke

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?

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.

Tell your pharmacist or doctor if you are using any other medicines to treat skin conditions of the scalp, as other topically applied skin treatments may affect the way that REGAINE® works.

Your treatment with REGAINE® may not be as effective, if you take diethylcarbamazine or paracetamol regularly.

While you are using REGAINE®

- An increase in hair shedding may occur within the first 2-6 weeks of treatment. This increase in hair loss is expected and temporary. However, if it continues, see your pharmacist or doctor.
- 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®.
- Dizziness or decrease in blood pressure may occur. If affected, do not drive or operate machinery.
- 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 foam 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.
- 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® foam after applying it. 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 hairdresser/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.
- If you need to apply a sunscreen to the scalp, it 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.

How and when to use REGAINE®

- REGAINE® must only be applied when the hair and scalp are completely dry.
- REGAINE® must only be applied to a healthy and intact scalp.
- **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:

Before application, rinse your hands with cold water and dry thoroughly. For best results, apply MEN'S REGAINE® EXTRA STRENGTH FOAM sparingly, twice a day to the hair loss area, preferably in the morning and at night. Massage the foam lightly into your scalp. Wash your hands thoroughly afterwards. Up to half a capful of foam should be used. Men with a small area of hair loss may need to use less.

Using more than the recommended amount will not improve results. Each can should last approximately one month if used as directed. Never take REGAINE® by mouth or apply it to other parts of the body.

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.

How to open and apply:

1. Within the hair thinning area, part the hair into one or more rows to maximise scalp exposure.
2. Open the container by matching the arrow on the can ring with the line on the cap. Pull off cap.
3. The foam may begin to melt on contact with your warm skin. If your fingers are warm, rinse them in cold water first. Be sure to dry them thoroughly before handling the foam.
4. Hold the can straight upside down and press the nozzle to dispense the topical foam product into the palm of your hand. The total amount of foam should not exceed half a capful.
5. Using your fingers, spread the foam over the hair loss area and gently massage into the scalp and then wash your hands well.
6. After each use, close the container by snapping the cap back onto the can, to make the cap child resistant.

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 half a capful 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®.

If you get any side effects that worry you, talk to your pharmacist or doctor as soon as

you can. You may be advised to stop using REGAINE®.

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 REGAINE®. 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 REGAINE® is being applied
- dry skin/scalp flaking
- REGAINE® contains alcohol which could cause burning or irritation to the eyes, mouth, nose and ears, or sensitive skin areas
- excessive or unwanted hair grown on other parts of the body. Unwanted hair growth may be caused by the transfer of REGAINE® to areas other than the scalp, or by the absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of REGAINE®
- increased hair loss

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

Some patients have experienced changes in hair colour and/or texture while using REGAINE®.

Stop use and tell your pharmacist or doctor as soon as possible if you notice any of the following:

- rapid heart rate or change in heart rate
- decrease in blood pressure or blood pressure changes
- unexplained rapid weight gain
- swelling or puffiness of hands, face, ankles, or stomach
- dizziness, light-headedness, or fainting
- problems with vision
- shortness of breath
- headaches
- persistent redness or irritation of the scalp

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

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.

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 REGAINE® is accidentally swallowed

Accidental ingestion may cause serious side effects. If REGAINE® is accidentally swallowed contact your nearest hospital or Poisons Information Centre (telephone number AUS: 13 11 26, NZ: 0800 764 766) immediately. Some of the symptoms which you may experience are fast heart rate, low blood pressure (light-headedness or fainting), swelling or puffiness of the body.

How to store REGAINE®

- Keep REGAINE® in a cool place where the temperature stays below 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.
- The expiry date is printed on the can. Do not use REGAINE® after this date has passed.
- Return any unused foam to your pharmacist.

Description

MEN'S REGAINE® EXTRA STRENGTH FOAM is available as:

- Foam containing minoxidil 5% w/w. The Identification Number for MEN'S REGAINE® EXTRA STRENGTH FOAM is AUST R 277919.

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.

Who supplies your medicine

REGAINE® is supplied by:

**Johnson & Johnson Pacific
AUSTRALIA • NEW ZEALAND**
45 Jones Street, Ultimo NSW 2007,
AUSTRALIA and Auckland, NEW
ZEALAND

® Registered Trademark

Approved: 12 September 2008