

Formula ONE Hair Loss Balm

Minoxidil 10%, Biotin 0.2%, and Caffeine 0.05%

This leaflet provides important information about using [medicine name].

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using the hair loss balm.

WHY AM I USING Formula ONE Hair Loss Balm?

This balm is indicated for the treatment of hair loss and promoting hair regrowth in individuals experiencing male or female pattern baldness. It has been compounded specifically for you as there is no equivalent or suitable TGA-approved medicine commercially available in Australia.

WHAT SHOULD I KNOW BEFORE I USE Hair Loss Balm?

WARNINGS

Do not use this medication if:

- Do not use this balm if you are allergic to any of the ingredients.
- Always check the ingredients to make sure you can use this medicine.
- your hair loss is patchy, and/or sudden or unexplained.
- Your scalp is red, inflamed, irritated, infected or painful.
- You are a woman who is pregnant or breastfeeding.
- The expiry date (EXP) printed on the pack has passed.

CHECK WITH YOUR DOCTOR IF YOU:

- have any other medical conditions.
- take any medicine for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section *Are there any side effects?*

PREGNANCY AND BREASTFEEDING

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect The Hair Loss Balm.

HOW DO I USE Formula ONE Hair Loss Balm?

HOW MUCH TO TAKE /USE

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



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While using the Formula ONE Hair Loss Balm

- 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 this medication. It is also important to tell your doctor that you are using this medication if your doctor is going to prescribe for you another type of medicine to take at the same time as using Formula ONE Hair Loss Balm.
- Dizziness or decrease in blood pressure may occur. If affected, do not drive or operate machinery.
- If after 6 months of using this medication 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 or stop using without first asking your pharmacist or doctor for advice.
- Do not use this medication more than two times a day, and do not use more solution than your pharmacist or doctor tells you to. Using more than the recommended dose or more often will not improve results.
- This medication is for external use only. Never take this medication orally to help hair growth. This could lead to serious side effects.
- Do not apply this medication to any area of the body other than the scalp.
- It is not necessary to shampoo before applying this medication, however if you do wash your hair wait until your hair is absolutely dry before using this medication 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 hair loss solution. As Formulæ ONE Hair Loss Balm 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 solution to your eyes, mouth, nose, ears, or broken or irritated skin, bathe the area with large amounts of cool tap water.

IF YOU USE TOO MUCH

If you think that you have used too much of this medication, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

WHAT SHOULD I KNOW WHILE USING this medication.

- Hair sprays and other common hair products can be used while using this medication, however the medication 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



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that you are using this medication. It may be best to stop using this medication 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 this medication to ensure that the sunscreen does not interfere with the effectiveness of the medication. 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 this medication 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 this medication before wearing your hat.
- You can use this medication after swimming as long as your scalp is dry.

LOOKING AFTER YOUR MEDICINE

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

GETTING RID OF ANY UNWANTED MEDICINE

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

ARE THERE ANY SIDE EFFECTS?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However,

some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

- *allergic-type reactions*
- *itching and other skin irritations of the treated area of the scalp*
- *eczema*
- *redness of the scalp where the solution is being applied*
- *dry skin/scalp flaking*
- *Formula ONE Hair Loss Balm 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 solution 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 this medication.*
- *increased hair loss*

These are the more common side effects of this medication. For the most part these have been mild. Stop use and tell your pharmacist or doctor as soon as possible if you notice any of the following:

- *rapid heart rate*
- *decrease in blood pressure or blood pressure changes*
- *unexplained rapid weight gain*
- *swelling or puffiness of hands, face, ankles, or stomach*
- *dizziness, lightheadedness, or fainting*
- *problems with vision*
- *persistent redness or irritation of the scalp*

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



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side effects are rare. If any of the following occur stop using this medication 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.

Other side effects not listed here may occur in some people.

PHARMACY CONTACT

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