

# Vello-5™

## Topical Solution 5% w/v

### What is Vello-5?

Vello-5 Topical Solution contains Minoxidil 5% w/v and is to be used only on your scalp. It is colourless to slightly yellow transparent liquid, with a weak, ethereal, vinous odour. Available in pack size of 60ml.

### What is this medication used for?

Vello-5 is used for the treatment of hair loss in men and women. It stimulates hair growth and stabilizes hair loss in patients experiencing hair loss or hair thinning.

### How effective is Vello-5 in regrowing hair?

It is important for you to understand that Vello-5 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 Vello-5. You should discuss what results you might expect from treatment with Vello-5 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 Vello-5, 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 Vello-5 have reported that the loss of hair is slowed during treatment. Treatment with Vello-5 is a long-term therapy for hair regrowth. If you respond to treatment, you will need to continue to use Vello-5 in order to keep the new hair and also to stop additional hair loss. If you stop using Vello-5, 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.

### How to use this medication?

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

Apply 10 sprays (1ml) at a time, 2 times a day to the hair loss area of your scalp, preferably morning and night. Massage scalp gently with fingertips. The total dosage in a day should not exceed 20 sprays (2ml). Fingertips are used to facilitate drug application, hands should be washed 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. Response to treatment with Vello-5 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:  
Pump spray applicator: this is useful for large areas. Aim the pump at the centre of the bald area, press once and spread with fingertips over the entire bald area. Repeat for a total of 10 times to apply a dose of 1 ml. Avoid breathing spray mist.

Extended spray-tip applicator: this is useful for small areas, or under hair. The pump spray applicator must be in place in order to use this additional applicator. Use in the same way as the pump spray. Avoid breathing spray mist.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### How long to use this medication?

You should continue to use Vello-5 as directed by your pharmacist or doctor. It has been shown that use of Vello-5 may be required for at least four months before you will see the evidence of cosmetically acceptable hair growth. If after 6 months of using Vello-5 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. If hair regrowth occurs, twice daily applications are necessary for continued hair growth. Once Vello-5 is stopped, the appearance of your hair will return to how it was before you started to use Vello-5.

### When should you not take this medicine?

- Do not use Vello-5 if:
- you have known hypersensitivity to any ingredients in this medicine.
  - you do not have a family history of hair loss
  - your hair loss is patchy and/or sudden, or if the reason for hair loss is unknown.
  - the hair loss is due to childbirth.
  - your scalp is red, inflamed, irritated, infected or painful.
  - you are currently using any topical medications on the scalp.
  - you are under 18 or over 65 years of age.
  - you are pregnant or breastfeeding.

### Care that should be taken when taking this medicine:

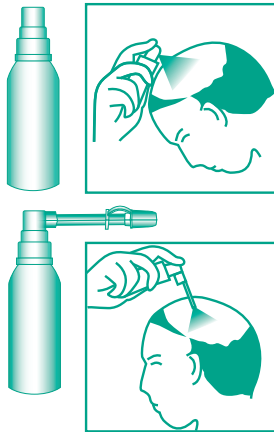
- Tell your pharmacist or doctor about medical problems you have now or have had in the past. While you are using Vello-5
- If you are going to have any laboratory tests (e.g. blood or urine), tell your doctor that you are using Vello-5 if your doctor is going to prescribe for you another type of medicine to take at the same time as using Vello-5.
  - Do not change your dose of Vello-5 or stop using Vello-5 without first asking your pharmacist or doctor for advice.
  - Do not use Vello-5 more than two times a day, and do not use more solution than your pharmacist or doctor tells you to.
  - Vello-5 is for external use only. Never take Vello-5 orally to help hair growth. This could lead to serious side effects.
  - Do not apply Vello-5 to any area of the body other than the scalp.
  - The use of Vello-5 may cause dizziness or hypotension. If affected, do not drive or operate machinery.
  - It is not necessary to shampoo before applying Vello-5. However, if you do wash your hair, wait until your hair is absolutely dry before using Vello-5 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 Vello-5 solution. As Vello-5 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 Vello-5 to your eyes, mouth, nose, ears, or broken or irritated skin, bathe the area with large amounts of cool tap water.
  - Use of Vello-5 in conjunction with other products should be discussed with your pharmacist or doctor.

Tell your doctor or pharmacist if:

- you are pregnant or plan to get pregnant.
- you are breastfeeding
- you have any heart problems.

### Common questions about using Vello-5

- Hair sprays and other common hair products can be used while using Vello-5, however Vello-5 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 Vello-5. It may be best to stop using Vello-5 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 Vello-5 to ensure that the sunscreen does not interfere with the effectiveness of Vello-5. If it is not possible, the sunscreen should be applied no sooner than two hours after application.
- You can use Vello-5 after swimming as long as your scalp is dry.
- Vello-5 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.

### Interactions with other medications

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Medicine interactions can change the way a medicine works. Your pharmacist or doctor will be able to tell you what to do when using Vello-5 with other medicines.

Do not use Vello-5 concomitantly with other medications applied on the scalp such as corticosteroids, tretinoin or anthralin which 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 Vello-5 may not be as effective if you take diethyl-carbamazine or paracetamol regularly.

### Side effects

Along with its desired effects, a medicine may cause some unwanted effects. Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using Vello-5.

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  |                                  |

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

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

- |   |                                  |                         |
|---|----------------------------------|-------------------------|
| • Low blood pressure                            | • Chest pain                     | • Rapid heart rate      |
| • Faintness or dizziness                        | • Sudden unexplained weight gain | • Swollen hands or feet |
| • Persistent redness or irritation of the scalp |                                  |                         |

Like all medicines, this product can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If any of the following occur, stop using Vello-5 and tell your doctor immediately or go to casualty at your nearest hospital:

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

### When to seek further medical advice?

Inform your doctor and/or pharmacist immediately if you experience any allergic symptoms or symptoms of side effects.

Consult your doctor if the symptoms do not get better, worsen while taking this medicine.

### What should you do if you miss a dose?

If you miss a dose, take it as soon as possible. However, if it is almost time for next dose, skip the missed dose and back to your regular dosing schedule. Do not apply more than 1 ml of Vello-5 and do not use more than twice daily to make up for the dose you missed.

### What to do when you have taken more than the recommended dosage?

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine, or accidentally swallow Vello-5. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Overdosage may occur when higher than recommended doses are applied to larger surface areas of the body or areas other than the scalp by increasing systemic absorption of minoxidil. Accidental ingestion may cause serious heart problems. Therefore, keep this product out of reach of children. 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 should this medication be kept?

Store below 30°C.  
Keep medicine out of the sight and reach of children.  
The expiry date of this product is indicated on the packaging.

**List of excipients:** Ethanol 96%, Propylene Glycol and Purified Water.

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Manufactured by  
**Xepa-Soul Pattinson (Malaysia) Sdn Bhd**  
1-5 Cheng Industrial Estate, 75250, Melaka, Malaysia.

Product Registrant  
**Apex Pharma Marketing Pte Ltd**

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