

Topical Solution 5%w/v (Minoxidil 50mg/ml)

What is in this leaflet

1. What Vello-5 is used for
2. How Vello-5 works
3. Before you use Vello-5
4. How to use Vello-5
5. While you are using it
6. Side effects
7. Storage and Disposal of Vello-5
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Vello-5 is used for

Vello-5 is used to stimulate hair growth and is used in the treatment of hair loss (alopecia androgenetica).

How Vello-5 works

The mechanism by which minoxidil stimulates hair growth is not fully understood, but minoxidil can reverse the hair loss process of androgenetic alopecia by increasing the diameter of the hair shaft, stimulating anagen growth, prolonging the anagen phase and stimulating anagen recovery from the telogen phase. As a peripheral vasodilator, minoxidil enhances microcirculation to hair follicles. The Vascular Endothelial Growth Factor (VEGF) is stimulated by minoxidil and VEGF is presumably responsible for the increased capillary fenestration, indicative of a high metabolic activity that observed during the anagen phase.

Before you use Vello-5

- When you must not to use it

- Do not use Vello-5 if you are known hypersensitivity to any ingredients in this medicine.
- Should not be applied to inflamed scalp skin or areas affected by psoriasis, severe sunburn, or severe excoriations, because of the risk of increased absorption.

Pregnancy and lactation

- Do not take Vello-5 if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Vello-5 if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

- Tell your doctor or pharmacist if:
- You are pregnant or plan to get pregnant.
 - You are breast-feeding.

- Taking other medicines

- 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.
- Should not be used concomitantly with other medications applied on the scalp such as corticosteroids, tretinoin, dithranol or petrolatum, which alter the stratum corneum barrier. This would result in increased absorption of minoxidil if applied concurrently. Although it has not been demonstrated clinically, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

How to use Vello-5

- How much to use

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

Apply 10 sprays (1ml) at a time, 2 times a day to the areas of baldness or hair loss. 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.

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.

- When to use it

Use as directed by your doctor or pharmacist.

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.

- How long to use it

- Continue taking for as long as your doctor recommends.
- It may take twice daily applications for two months or more before evidence of hair growth can be expected. Users should discontinue treatment if there is no improvement after one year.
- If hair regrowth occurs, twice daily applications are necessary for continued hair growth. Anecdotal reports indicate that regrown hair may disappear three to four months after stopping the application of minoxidil solution and the balding process will continue.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

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. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Over dosage 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.

Signs and symptoms of minoxidil overdose would primarily be cardiovascular effects associated with sodium and water retention. Tachycardia, hypotension, dizziness and lethargy can also occur.

Treatment of minoxidil overdose should be symptomatic and supportive. Fluid retention can be managed with appropriate diuretic therapy. Clinically significant tachycardia can be controlled by administration of a beta-adrenergic blocking agent.

While you are using it**Things you must do**

- This product is for topical use only.
- Take your medicine exactly as your doctor has told you.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not exceed the stated dose.
- Do not take any new medicines without consulting your doctor.
- Do not give this product to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Please always consult your doctor or pharmacist before using this product especially when there is a known to hypersensitivity.
- The 5% minoxidil solution is not recommended for women.
- Topical application of minoxidil should be restricted to the scalp.
- Patients being treated for hypertension should be monitored if topical minoxidil is used concurrently.
- Vello-5 will cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), the area should be bathed with copious amounts of cool tap water.

Side effects

- Topical application of minoxidil may be associated with contact dermatitis, pruritus, local burning, and flushing; sufficient may be absorbed to produce systemic adverse effects.
- Changes in hair colour or texture may occur.

Immune System Disorders

Common: Hypersensitivity reactions (including face oedema, generalised erythema, pruritus generalised, swelling face, and throat tightness).

Not known: Angioedema (including lip oedema, lip swelling, oedema mouth, oropharyngeal swelling, pharyngeal oedema, swollen tongue and tongue oedema).

Psychiatric Disorders

Not known: Depressed mood.

Nervous System Disorders

Very common: Headache.

Uncommon: Dizziness.

Eye disorders

Not known: Eye irritation.

Cardiac disorders

Common: Chest pain.

Uncommon: Palpitations.

Not known: Heart rate increased.

Vascular disorders

Not known: Hypotension.

Respiratory, thoracic and mediastinal disorders

Uncommon: Dyspnoea.

Gastrointestinal Disorders

Uncommon: Nausea.

Not known: Vomiting.

Skin and subcutaneous tissue disorders

Common: Hypertrichosis (unwanted non-scalp hair including facial hair growth in women), Pruritus (including rash pruritic generalised and eye pruritus), Rash (including pustular, popular, generalised, vestibular and macular rash), Dermatitis (including contact, allergic, atopic and seborrhoeic dermatitis).

Rare: Changes in hair texture.

Not known: Dry skin, Skin exfoliation (including exfoliative rash and dermatitis exfoliative), Acne (acneiform rash), Temporary hair loss, Changes in hair colour.

General disorders and administration site conditions

Common: Oedema peripheral.

Not known: 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 exfoliation, dermatitis, blistering, bleeding and ulceration).

Investigations

Common: Weight increased.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my. [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Vello-5**Storage**

Store below 30°C.

Keep out of reach of children.

The expiry date of this product is indicated on the packaging.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description**How it looks like**

Each bottle contains Colourless to slightly yellow transparent liquid, with a weak, ethereal, vinous odour. Available in pack size of 60ml.

Ingredients**Active ingredients**

Minoxidil

Inactive ingredients

Ethanol, Propylene Glycol and Purified Water.

MAL Number

MAL 18126004AZ

Manufacturer and Product Registration Holder

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