

Aetos Minoxidil Topical Solution 5%w/v

Minoxidil (5%w/v)

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What Aetos Minoxidil Topical Solution 5%w/v is used for

Aetos Minoxidil Topical Solution 5%w/v contains a medicine called Minoxidil.

Aetos Minoxidil is used to stimulate hair growth and is used in the treatment of hair loss (alopecia androgenetica)

How Aetos Minoxidil Topical Solution 5%w/v 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 Aetos Minoxidil Topical Solution 5%w/v

- When you must not use it

Do not take this medicinal product if you have the following conditions:

- Do not use Aetos Minoxidil if you are known hypersensitivity to any ingredients in this medicine.
- Do not apply Aetos Minoxidil to inflamed scalp skin or areas affected by psoriasis, severe sunburn, or severe excoriations, because of the risk of increased absorption
- Do not use this product if you are under the age of 18 or over the age of 65.
- Do not use this product if you have ever had a bad reaction to alcohol and propylene glycol

Pregnancy and lactation

Aetos Minoxidil should not be used during pregnancy or lactation.

- Before you start use it

Tell your doctor or pharmacist before using Aetos Minoxidil Topical Solution 5%w/v:

- If you are unsure whether your scalp is normal and healthy.
- If you suffer from heart disease, including abnormal heart rhythms or rates, angina or chest pains and/ or circulation disorders.
- If you are taking or using any other medicines simultaneously to lower your blood pressure

- 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.

Inform your doctor or pharmacist if you are using creams, ointments or lotions used to treat scalp conditions:

- Dithranol – used to treat psoriasis.

- Tretinoin – used to treat acne or other skin disorders.
- Corticosteroids – a type of anti-inflammatory.
- Petrolatum - a common ingredient in hair wax or gel

How to use Aetos Minoxidil Topical Solution 5%w/v

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 much to use

A total dose of 6 sprays (equivalent to 1 ml) Aetos Minoxidil Topical Solution 5%w/v should be applied twice per day to the scalp, beginning at the center of the affected area. This dose should be used regardless of the size of the affected area. The total daily dose should not exceed 2 ml (12 sprays).

Apply Aetos Minoxidil Topical Solution 5%w/v when the hair and scalp are thoroughly dry. After applying Aetos Minoxidil Topical Solution 5%w/v, wash hands thoroughly.

- When to use it

To be applied twice per day to the scalp.

- How long to use it

The studies conducted to date indicate that 4 or more months of treatment with Aetos Minoxidil Solution 5%w/v may be required for noticeable hair growth. Interruption of treatment may induce a return to the initial condition within 3 to 4 months.

- If you forget to use it

If you miss an application, just apply as soon as you remember. Do not apply twice as much. Ensure that you do not exceed 2mL in one day.

- If you use too much (overdose)

In case of suspicion of overdose or intoxication with this medicinal product, contact your doctor immediately or go to the Emergency Department of your nearest hospital, for symptomatic treatment.

While you are using it

- Things you must do

It should only be applied directly to the scalp area.

The hair and scalp should be thoroughly dry before topical application of Aetos Minoxidil Topical Solution 5%w/v.

The solution should be spread with your fingertips to ensure that the medicinal product is uniformly distributed.

Wash your hands thoroughly after each application.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Aetos Minoxidil Topical Solution 5%w/v.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not use Aetos Minoxidil Topical Solution 5%w/v after the expiry date.

- Things to be careful of

If minoxidil passes into the blood stream it can cause some side-effects related to low blood pressure such as chest pain, rapid heartbeat, faintness, dizziness, swollen hands and feet, persistent redness or irritation of the scalp. If you experience any of these side-effects, stop using the medicine and tell your doctor.

When Aetos Minoxidil Topical Solution 5%w/v is used as recommended, it is extremely unlikely that these effects will occur. However there is a chance the drug could get into the blood stream if it is over used or if there is a scalp condition such as psoriasis present.

Therefore it is very important that you use your medicine as recommended and follow the instructions very carefully.

See section on "How to use Aetos Minoxidil Topical Solution 5%w/v".

Side effects

Like all medicines, Aetos Minoxidil Topical Solution 5%w/v 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. Do not be alarmed by the following list of possible side effects. You may not experience any of them.

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

- Swelling of the face, lips, tongue and/or throat.
- Throat tightness
- Palpitations and/or fast heart beat
- Breathing difficulty.
- Changes such as skin rash and redness leading to itching, dry and flaking skin and/or swelling where the product is applied, or around the ears and face, blistering, bleeding and ulcers
- Chest pain
- Swelling in the feet and/or legs
- Sudden, unexplained weight gain
- Dizziness, feeling faint due to low blood pressure

Other side effects not listed above may also occur in some people.

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 Aetos Minoxidil Topical Solution 5%w/v

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C. Keep the bottle tightly closed.

Shelf-life after first opening: 12 months.

- Disposal

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

Product Description

- What it looks like

A clear, colourless to yellowish homogeneous topical solution which is free from particles in suspension.

- Ingredients

- Active ingredient
Minoxidil 50mg/ml

- Inactive ingredients
Propylene glycol, Ethanol 96%

- MAL number:

MAL23106018AZ

Manufacturer

MEDINFAR MANUFACTURING, S.A.
Parque Industrial Armando Martins
Tavares,
Rua Outeiro da Armada, No 5,
Condeixa-a-Nova,
3150-194 Sebal,
Portugal.

Product Registration Holder

Aetos Pharma Sdn Bhd
66B, Tingkat 2, Jalan Cerdas,
Taman Connaught,
56000 Kuala Lumpur

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