

AVOXIDIL Topical Solution 5%w/v

Minoxidil 5%w/v

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What Avoxidil is used for

The name of your medicine is Avoxidil Topical Solution 5%w/v (called 'Avoxidil' in this leaflet). Avoxidil contains a medicine called Minoxidil.

Avoxidil is used to treat baldness and hair loss in men and women. It stimulates hair growth and stabilize hair loss in baldness and hair loss.

How Avoxidil works

Its mechanism of action is not known. However, when applied topically, minoxidil has been shown to stimulate hair growth in individuals with problems of baldness and hair loss.

It takes 4 months or more for hair to start growing and growth of new hair will stop upon discontinuation. Pre-treatment appearance will be restored within 3-4 months.

Before you use Avoxidil**When you must not use it.**

Do not apply this medicine to other than your scalp.

Do not use this medicine if you are:

- under the age of 18
- allergic (hypersensitive) to Minoxidil, alcohol or propylene glycol.
- having hair loss caused by drug treatment.
- having total baldness or complete loss of all body hair.
- having unknown cause of hair loss, or it is sudden and unexpected.
- having **high blood pressure**, even if it is not being treated.

- having any **condition that affects your scalp**, including sunburn and psoriasis.
- having a **shaved scalp**.
- using **creams, ointments or lotions** used to treat scalp conditions
- having any kind of dressing or bandage on your scalp.

Before you start to use it:

This medicine is for external use only. Check with your doctor or pharmacist before taking this medicine:

- 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 including medicines called "vasodilators"
 - e.g. hydrazaline. There is potential risk that Avoxidil may interact with these medicines and increase their effect.
- If you are not sure about the medicine you are taking or using, show the bottle or pack to your doctor or pharmacist
- If you are pregnant or planning to become pregnant.
- If you are breast feeding. You should choose to bottle feed your baby or not take Avoxidil.

Taking other medicines

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Avoxidil and certain other medicines may interact with each other.

How to use Avoxidil**How much to use:**

A total dose of 1 mL Avoxidil should be applied twice per day to the scalp, beginning at the center of the affected area, regardless of the size of the affected area. Please refer to the last page for the section on "*Using the*

Spray applicator" in order to properly apply this medicine.

The total daily dose should not exceed 2 mL.

Do not apply Avoxidil to any other area of the body.

When to use it:

Avoxidil can be applied anytime of the day. Best to apply after the hair and scalp are thoroughly dry. When in use, avoid inhalation of spray mist.

How long to use it:

- You may need to use this medicine for at least 2 months before you see new hair growth, this is because hair growth is a slow process.
- Hair growth may be soft and downy at the start but should eventually become the same as normal hair.
- Once the hair has begun to re-grow, you need to continue using this medicine.
- When you stop using the medicine, the hair that has re-growth may disappear after 3-4 months and the balding/hair loss process will continue.
- If you have no improvement in your hair growth after one year of use, you should discontinue treatment.
- If at any time during your treatment you are concerned you should consult your doctor or pharmacist

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 take too much (overdose):

If you apply too much Avoxidil, immediately wash off with plenty of water.

Call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.

If anyone, including a child, swallows any of the solution, take them to a hospital immediately.

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While you are using Avoxidil

Things you must do.

- It should only be applied directly to the scalp area
- Massage lightly into the scalp after application.
- Wash your hands thoroughly before and after applying the solution and rinse other areas that have come into contact with the solution.
- Make sure your hair and scalp are completely dry before applying the solution.
- Choose an appropriate applicator to apply the medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do:

- Avoid breathing in the spray whilst applying to the scalp.
- Do not apply to areas of the body other than the scalp

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 heart beat, 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 Avoxidil 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 Avoxidil.'
- Warning Flammable Liquid. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Avoid exposure of the container and contents to naked flames during use, storage and disposal.

Keep container tightly closed. Store in well-ventilated place. Keep cool.

- Avoid contact with the eyes, mouth, broken skin and sensitive areas. If the solution is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water.
- Do not apply to areas of the body other than the scalp.
- Exceeding the recommended dose will NOT re-grow your hair any more quickly and you have an increased likelihood of getting side-effects.
- Accidental ingestion may cause serious cardiac adverse events. Therefore this product has to be kept out of the reach of children.

Side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

If you experience any of the following, stop using the medicine and talk to your doctor:

- Low blood pressure.
- Fast heart beat or an increased awareness of the heart beat (palpitations).
- Faintness or dizziness.
- Swollen hands or feet, shortness of breath.
- Headache
- Itching, dermatitis or excessive hair growth.
- Eye irritation.
- Vomiting or nausea.
- Scalp irritation such as local redness, dryness, flaky skin have all been reported. This may be due to propylene glycol in the product. This is usually only a temporary effect, but if it is persistent you should stop using this product.
- Temporary hair loss may occur during the first 2-6 weeks of use. This is likely to be as a result of a change within the growth cycle and it should stop within a couple of weeks. If this hair loss continues for longer than two weeks, stop using the product and talk to your doctor.

- Change in hair color and/ or texture may occur. If this happens you should stop using this medicine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Avoxidil

Storage:

- Keep out of the reach and sight of children.
- Do not use Avoxidil after the expiry date refers to the last day on the carton. The expiry date refers to the last day of that month.
- Store in the original pack in a dry place at or below 30°C.
- Warning Flammable Liquid. Keep away from heat/sparks/open flames/hot surfaces- No smoking. Avoid exposure of the container and contents to naked flames during use, storage and disposal.
- Do not use Avoxidil if the color turns dark or there are other visible signs of deterioration.

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

What it looks like:

Avoxidil Topical Solution is a colorless to slight yellowish clear liquid. It is packed in a HDPE plastic bottle of 60mL, with a PP spray applicator.

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Using the Spray applicator

The method of application varies according to the disposable applicator used, as indicated below. Choose which option is best for you.

Option-1: PUMP SPRAY APPLICATOR:

This applicator works best for applying Avoxidil to large areas of the scalp.

Instructions as follows:

1. Remove large outer cap and put it aside.
2. Remove small inner cap and discard it.
2. Insert the pump spray applicator into bottle and screw on firmly.
3. After aiming the pump toward the center of the bald area of the scalp, press the pump once and spread Avoxidil with fingertips to cover all of the bald area.
4. Repeat for a total of 7 times, to apply a dose of 1 mL of solution.
5. Avoid breathing spray mist. Place outer cap back on bottle when not in use.
6. Place large outer cap on bottle when not in use.
7. After applying Avoxidil thoroughly wash hands and other areas than the scalp that was in contact with Avoxidil.

Option-2: EXTENDED SPRAY-TIP APPLICATOR:

This applicator works best for applying Avoxidil to small areas of the scalp and under hair.

Instructions as follows:

1. The pump spray applicator must be on the bottle to use the extended tip applicator. Follow steps 1 and 2 for the pump spray applicator first.
2. Then remove small spray head from top of pump spray applicator; fit the extended spray-tip applicator onto the spray shaft

and push down firmly. Remove the small cap on the end of the extended tip and put to one side.

3. After aiming the pump toward the center of the bald area of the scalp, press the pump once and spread Avoxidil with fingertips to cover all of the bald area.
4. Repeat for a total of 7 times, to apply a dose of 1 mL of solution.
5. After applying Avoxidil wash hands thoroughly.

Ingredients in Avoxidil

Active ingredients:

Minoxidil

Inactive ingredients:

Propylene Glycol and alcohol.

Manufacturer

Sinphar Pharmaceutical Co., Ltd.
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Product Registration Holder:

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