

Read this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- This medicine is used to treat hereditary hair loss in women aged 18 – 65 years.
- Do not apply to other areas of the body other than the scalp. If accidentally applied rinse thoroughly with plenty of water. **See section 2**
- This medicine is for external use only and should only be applied to your scalp. **See section 3**
- This product is flammable and should be used and disposed of carefully. See Special Warnings Relating to Avogain Solution. **See section 2**

In this leaflet:

1. What Avogain Solution is and what it is used for.
2. What you need to know before you use Avogain Solution.
3. How to use Avogain Solution.
4. Possible side effects
5. How to store Avogain Solution.
6. Further information.

1- What is Avogain Solution and what it is used for:

Avogain is a medicine used to treat common hereditary hair loss in women aged 18-65 years, by preventing further hair loss and helping hair re-growth. It contains minoxidil which is thought to work by aiding the blood flow to the hair follicles on your scalp.

- The medicine is for use in women aged between 18 and 65 years.
- Avogain solution works best in women with hair loss or thinning at the top of the scalp.
- Those who are younger, have been losing hair for a short period of time or have a small area of baldness are likely to experience the best results.
- You are unlikely to benefit from Avogain if you have been bald for many years or have a large area of hair loss.

Hereditary hair loss is Recognizable because:

- Of the pattern of hair loss (see diagrams).
- It starts gradually and progresses.
- You have a family history of hair loss.
- No other symptoms are present with your hair loss.



2- What you need to know before you use Avogain Solution:

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not use this medicine...

- If you are **pregnant or breast-feeding**
- If you are **under the age of 18 or over the age of 65**.
- If you have had a **bad reaction** to minoxidil, ethanol, or propylene glycol.
- If you are not sure if your hair loss is hereditary.
- If you have hair loss caused by drug treatment.
- If you have total baldness or complete loss of all body hair.
- If the cause of your hair loss is unknown, or it is sudden and unexpected.
- If you have **high blood pressure**, even if it is not being treated.
- If you have any **condition that affects your scalp**, including sunburn and psoriasis.
- If you have a **shaved scalp**.
- If you are using **creams, ointments or lotions** used to treat scalp conditions, e.g.
 - 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.
- If you have any kind of dressing or bandage on your scalp.
- Unless you know that your scalp is normal and healthy.
- If any of these bullet points apply to you now or in the past, get advice from a doctor or pharmacist before using Avogain solution.

Talk to your doctor or pharmacist...

- If you are at all 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: certain blood pressure medicines called 'vasodilators' e.g. hydralazine. There is potential risk that minoxidil, the active ingredient in Avogain Solution 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 pharmacist. If any of these bullet points apply now or in the past, talk to a doctor or pharmacist.

If you are pregnant or breast-feeding:

This product should not be used if you are pregnant or breast-feeding.

Some of the ingredients can cause problems

- Propylene glycol may cause skin irritation.
- Avogain Solution 2% w/v contains ethanol (alcohol) which will cause burning and irritation if you get it in the eye. If you get Avogain Solution in your eye, mouth or on a cut or damaged skin, wash the area well with lots of cool tap water.

Special warnings relating to Avogain Solution:

- 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 Avogain solution 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 3
- 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 should be kept out of the reach of children.

3-How to use this medicine

Avogain is for topical and external use only. It should only be applied directly to the scalp area.

- Avoid breathing in the spray whilst applying to the scalp.
- Do not apply to areas of the body other than the scalp.
- 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.
- Applicator is designed to accurately release a 1 ml dose when used as described.

Daily dose for Adult Women:

Age	Dose
Female Adults aged 18 to 65 years	■ On a completely dry scalp and hair, apply a 1 ml dose to the total affected area twice daily using the best applicator for you. ■ The solution should be massaged lightly into the scalp after application.

- **Leave at least 12 hours between each use.**
- **Do not exceed 2 ml in a day.**
- **Do not use more than twice a day.**

Continued use of Avogain

- You may need to use this medicine twice daily for at least 4 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 twice a day for the growth to continue. In clinical trials 3 out of every 5 women reported hair re-growth after 48 weeks of continual use of this product.
- When you stop using the medicine, the hair that has re-grown 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.

Applying Avogain Solution

Pump Spray Applicator

1. This applicator works best for applying the solution to **large areas of the scalp**.
2. Remove large outer cap and put it to one side.



3. After aiming the pump toward the center of the bald area of the scalp, press the pump once and spread the solution with fingertips to cover all the bald area.
4. Repeat 5 more times. Avoid breathing spray mist.
5. Place outer cap back on bottle when not in use.
6. The total of 6 sprays will deliver the 1 ml dose of minoxidil that is required.
7. Wash your hands and any other areas other than your scalp which may have come in contact with this medicine.

If anyone uses too much

Seek immediate medical advice if anyone, including a child, uses too much of this medicine. Take the medicine and container with you.

If you forget to apply a dose of the solution

If you miss one or two applications just carry on as normal as if you had not missed the dose - **do not use twice as much or twice as often.**

If you accidentally swallow the solution

If anyone, including a child, swallows any of the solution, take them to a hospital immediately (with Avogain bottle if possible, as the doctor may like to have some idea of how much they have swallowed).

4-Possible 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 seek immediate medical help:

- Chest pain
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

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

- Allergic reactions including swollen face, skin redness or itching or throat tightness.
- 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.
- Sudden unexplained weight gain.
- Persistent local redness or rash.

Other effects which may occur include:

Very common (may affect more than 1 in 10 people)

-Headache.

Common (may affect up to 1 in 10 people)

-Itching, dermatitis or excessive hair growth.

Uncommon (may affect up to 1 in 100 people)

- 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.
- Acne-like rash, itchy rash, blistering, bleeding or ulceration.
- Unwanted non-scalp hair has been reported..
- (including facial hair growth in women).
- Always wash your hands thoroughly after application and if you accidentally apply the solution to parts of the body other than the scalp, rinse thoroughly with plenty of water.
- 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 Avogain.

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

5-How to store this medicine

Keep out of the sight and reach of children.

Store below 30°C, Don't freeze.

Shelf life: 2 Years.

Shelf life after first opening is 30 days.

Do not use after the expiry date on the box.

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.

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 protect the environment.

6-Contents of the pack and other information

Including one bottle 50 ml used for one month treatment, and pump spray applicator.

FURTHER INFORMATION ABOUT AVOGAIN SOLUTION:

Q If my hair growth is restored using Avogain Solution, what will the new hair look like?

A If you respond to treatment, your initial re-growth may at first be soft, downy ("vellus") hair and may be barely visible.

After further treatment, your hair re-growth may change and become the same color and thickness as the rest of your hair.

Q Is shampooing necessary before applying Avogain Solution?

A No, but if you do choose to shampoo, we recommend the use of a shampoo with a gentle cleansing and conditioning action that does not impede the absorption of Avogain Solution

Q If I do shampoo, how long must I wait before applying Avogain Solution?

A To be sure the scalp is thoroughly dry, it is recommended that Avogain Solution be applied one hour after shampooing.

Q Can I use a hair dryer with Avogain Solution?

A Yes, but not to dry the solution itself.

Q Can I use common hair styling preparations such as hair gels or hair sprays while using Avogain Solution?

A Yes, but Avogain Solution should be applied to the dry scalp before these other preparations are applied.

Q Can I have my hair dyed?

A Yes, you may; there is no need to change your hair care routine. However, you should tell your hair care professional that you are using Avogain Solution. To minimize breakage of existing hair, just ask that any massaging of your scalp be gentle, and that a comb with widely spaced, round teeth be used to avoid excessive pulling.

Q Can Avogain Solution be used with a sun-blocking agent?

A No. If you are planning to be in the sun after applying Avogain Solution, use headwear.

Q Can I apply Avogain Solution after swimming?

A Yes, as long as hair is dry. However, Avogain Solution should not be applied more frequently than twice daily.

Q How long will each bottle of Avogain Solution last?

A One bottle of Avogain Solution should last for 30 days (one month), if applied twice a day according to directions. As you reach the end of a month's supply, you should plan to renew it so that you do not miss a daily application.

Q Why do boxes always include new applicators?

Why not make refills available?

A Each pack comes with new applicators. So, you can be assured that the metering device is always delivering the correct amount of solution and that it has not become clogged or damaged over time.

Marketing Authorisation Holder and Manufacturer:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)
P.O.Box 4180 Riyadh 11491, Kingdom of Saudi Arabia
2nd Industrial City, Riyadh, Kingdom of Saudi Arabia
Tel: +966 (11) 2653948-2653427
Fax: +966 (11) 2654723

For further information about this medicinal product, or to report a suspected adverse drug event please contact the Marketing authorization Holder.
E-mail: pharmacovigilance@avalon.com.sa
Call: +966 (11) 4635247, Ext: 3328

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To report any side effect(s):

- Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC) • Fax: +966-11-205-7662 • Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340. • Toll free phone: 8002490000 • E-mail: npc.drug@sfd.a.gov.sa • Website: www.sfd.a.gov.sa/npc
• Other GCC States:
Please contact the relevant competent authority.
THIS IS A MEDICAMENT
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. -The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the period of treatment prescribed for you. - Do not repeat the same prescription without consulting your doctor. -Keep all medicaments out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists

This patient information leaflet is approved by the Saudi Food and Drug Authority

