

MINOXIL FORTE 5% dermal spray, solution

For external use on dry hair and scalp.

Available Without Prescription

Topical Hair Growth
Stimulant

Minoxidil
5%

Not for use under 18 or over 65 years of
age

ACTIVE INGREDIENT

One bottle (60 ml) of spray contains 3 g of minoxidil.

EXCIPIENTS

Propylene glycol, alcohol, purified water

PACKAGING

Bottle containing 60 ml solution

Carefully read this USER INSTRUCTION, as it contains important information for you.

This medicine is for you to treat a minor illness without a doctor's help, with the advice of your pharmacist. However, you still need to use Minoxil Forte carefully to get the best results.

Keep this leaflet. You may need to read it again later.

If you have additional questions, please consult your doctor or pharmacist.

This medicine has been prescribed for you personally, do not give it to others.

During the use of this medicine, inform your doctor that you are using this medicine when you go to the doctor or hospital.

Follow exactly what is written in this instruction. Do not use **higher or lower** doses than the recommended dose of the medicine.

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What is MINOXIL FORTE and what is it used for?

One bottle of MINOXIL FORTE (60 ml) contains 3 g of minoxidil.

MINOXIL FORTE is a topical hair growth stimulating medicine.

One bottle of MINOXIL FORTE (60 ml) contains a 30-day dose. Each spray (0.2 ml) contains 10 mg of minoxidil.

INDICATION 1

Androgenetic Alopecia (Male Pattern Baldness)

Used in long-term treatment to prevent hair loss and stimulate hair growth.

INDICATION 2

Alopecia Areata (Patchy Hair Loss)

Used to stimulate hair regrowth.

Before you use MINOXIL FORTE

This medicine is suitable for most people, but some people should not use it. If you have any doubts, consult your doctor or pharmacist.

Do NOT use MINOXIL FORTE in the following situations:

If you are hypersensitive to minoxidil, the active ingredient in MINOXIL FORTE, or to any of the other ingredients in the formulation.

If you are not sure if your hair loss is hereditary.

If your hair loss is due to drug treatment.

If you have complete baldness or complete hair loss over your entire body.

If the cause of your hair loss is unknown or if it is sudden and unexpected.

If you have high blood pressure, even if you are not being treated.

If you have any scalp conditions, including sunburn and psoriasis.

If you have skin diseases such as inflammation, redness, infection, irritation on your scalp.

If you are using a medicine containing Guanethidine.

If you are under 18 or over 65 years of age.

If your scalp has been shaved with a razor.

If you are using creams, ointments or lotions to treat scalp problems, such as:

Dithranol - used to treat psoriasis.

Tretinoin - used to treat acne or other skin conditions.

Corticosteroids - a type of anti-inflammatory.

Petrolatum - a common ingredient in hair wax or gel.

If you have any dressing or bandage on your scalp.

If you do not know if your scalp is normal and healthy.

If any of the above apply to you now or in the past, consult your doctor or pharmacist before using MINOXIL FORTE.

If you are unsure about the medicine you are taking or using, show the bottle or packaging to your pharmacist. If any of the above apply now or in the past, consult your doctor or pharmacist.

Use MINOXIL FORTE CAREFULLY in the following situations:

If you are not sure if your scalp is normal and healthy.

If you have heart disease, including abnormal heart rhythm or rate, chest pains and/or circulatory disorders.

If you are taking or using any other medicine, including:

Certain blood pressure medicines called "vasodilators", e.g., hydralazine. There is a risk that minoxidil, the active ingredient in Minoxil Forte Spray, may interact with these medicines and increase their effects.

If you have liver or kidney failure.

If you have cardiovascular disease.

If you are using diuretics or antihypertensive medicines.

Consult a doctor before using MINOXIL FORTE.

If these warnings apply to you now or at any time in the past, please consult your doctor.

Using MINOXIL FORTE with food and drink

There are no interactions with food and drink.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

There are insufficient studies in animals and pregnant women with topically applied minoxidil. Therefore, it should not be used in pregnant women.

If you realize that you are pregnant during your treatment, immediately consult your doctor or pharmacist.

Lactation

Consult your doctor or pharmacist before using the medicine.

It is known that minoxidil passes into breast milk, albeit in small amounts, during topical application.

It should not be used during lactation due to potential side effects.

Driving and using machines

MINOXIL FORTE may cause dizziness or low blood pressure. Considering the possibility of such side effects, do not drive or use machines.

Important information about some excipients in MINOXIL

The alcohol in MINOXIL FORTE may cause a burning sensation and irritation when it comes into contact with eyes, mucous membranes, or sensitive or broken skin areas. In case of contact with such areas, the contact area should be washed thoroughly with plenty of cold water.

The propylene glycol in MINOXIL FORTE may cause skin irritation.

Special warnings regarding MINOXIL FORTE

Topical minoxidil is indicated for the long-term treatment of Androgenetic Alopecia, for the prevention of hair loss, stimulation of hair growth, and for the stimulation of hair growth in the treatment of alopecia areata (sudden hair loss in patches). It should not be used for other types of hair loss. Topical minoxidil should not be used if there is no family history of hair loss, if hair loss is

sudden and/or patchy, if hair loss is congenital, or if the cause of hair loss is unknown.

If minoxidil enters the bloodstream, it can cause some side effects associated with low blood pressure, such as chest pain, rapid heartbeat, fainting, dizziness, swelling in 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 MINOXIL FORTE is used as recommended, the likelihood of these effects occurring is extremely low. However, if used excessively or if there is a scalp condition such as psoriasis, there is a chance of the medicine entering the bloodstream. Therefore, it is very important to use your medicine as recommended and follow the instructions very carefully.

Avoid contact with eyes, mouth, broken skin, and sensitive areas. If the solution accidentally gets on body areas other than the scalp, rinse thoroughly with plenty of water.

Do not apply to body areas other than the scalp.

Exceeding the recommended dose will **NOT grow your hair faster** and will **increase your chances of experiencing side effects**.

Accidental ingestion may cause serious cardiac side effects. Therefore, this product should be kept out of reach of children.

Some patients have experienced changes in hair color and/or texture while using this product.

Some consumers have reported increased hair shedding with the start of minoxidil treatment. This is most likely due to minoxidil shifting hairs from the resting phase to the growth phase (old hairs fall out as new hairs grow in their place). This temporary increase in hair shedding usually occurs two to six weeks after starting treatment and subsides within a few weeks. If shedding persists (> 2 weeks), users should stop using MINOXIL FORTE and consult their doctor. Users should be aware of this during long-term use of MINOXIL FORTE and consult their doctor.

Use with other medicines

If you are using a diuretic or another blood pressure-lowering medicine, do not use it without consulting a doctor.

If you are using a blood pressure-lowering medicine known as "Guanethidine", do not use MINOXIL FORTE.

Do not use MINOXIL FORTE with other medicines applied to the scalp.

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist about them.

How to use MINOXIL FORTE?

MINOXIL FORTE is for topical (surface) and external use only. It should only be applied directly to the scalp.

Instructions for proper use and dose/frequency of application:

Apply MINOXIL FORTE to the area of hair loss; 5 sprays (1 ml) twice a day, morning and evening.

Do not use MINOXIL FORTE anywhere else on your body except for dry hair and scalp.

If it accidentally comes into contact with an area other than dry hair and scalp, wash the area thoroughly with plenty of water.

MINOXIL FORTE should be discontinued 24 hours before any chemical hair treatments (dye, perm, etc.).

Hair spray, gel, shampoo, or other similar chemical hair products should be used at least 30 minutes after MINOXIL FORTE application.

Since sunscreens may reduce the effect of MINOXIL FORTE, they should be applied at least 4 hours after MINOXIL FORTE application to the scalp.

Do not stop treatment early; because MINOXIL FORTE is used for a long time to prevent hair loss and promote hair growth. Hair

growth is seen after 4 to 6 months of continuous application, with maximum effect at the end of 12 months.

Remember to use your medicine on time.

Follow these instructions unless your doctor gives you different advice.

Method of administration:

Spray MINOXIL FORTE once onto the area of hair loss, then spread it by massaging with your fingers.

Repeat this process 5 times, then wash your hands thoroughly.

Do not exceed 5 sprays (1 ml), regardless of the size of the area.

One bottle of MINOXIL FORTE contains a 30-day dose.

MINOXIL FORTE is for external use. Do not use orally or by inhalation, and do not drink it.

In case of accidental ingestion of minoxidil, a cardiovascular system picture characterized by fluid retention and palpitation is likely to occur. In such a case, fluid retention can be corrected with appropriate diuretic treatment. Clinically significant palpitation can be controlled with a beta-blocker (a blood pressure-lowering medicine). If hypotension develops, it should be treated with fluid replacement. Medicines such as norepinephrine and epinephrine should be avoided due to their excessive cardiac stimulant effects. There is no specific antidote.

If you have the impression that the effect of MINOXIL FORTE is too strong or too weak, talk to your doctor or pharmacist.

Different age groups

Use in children:

Not to be used in children under 18 years of age.

Use in the elderly:

Not to be used in individuals over 65 years of age.

Special use cases:

Kidney/Liver failure:

Considering the possibility that the metabolism or renal elimination of the drug may be affected in patients with liver or kidney failure, such patients should not use MINOXIL FORTE without consulting a doctor.

If you have used more MINOXIL FORTE than you should:

If you have used more MINOXIL FORTE than you should, talk to a doctor or pharmacist. If you have used more of the medicine than you should (including children), immediately seek medical attention at a healthcare facility, taking the medicine and its packaging with you.

If you forget to use MINOXIL FORTE:

Do not take a double dose to make up for forgotten doses.

If you forget to use MINOXIL FORTE, continue with the normal doses the next day.

Effects that may occur when treatment with MINOXIL FORTE is discontinued

When treatment is discontinued; the benefit provided by the treatment disappears, and hair loss restarts.

What are the possible side effects?

Like all medicines, MINOXIL FORTE may cause side effects in people who are sensitive to the ingredients it contains.

Very common: May affect at least 1 in 10 patients.

Common: May affect less than 1 in 10 patients but more than 1 in 100 patients.

Uncommon: May affect less than 1 in 100 patients but more than 1 in 1,000 patients.

Rare: May affect less than 1 in 1,000 patients but more than 1 in 10,000 patients.

Very rare: May affect less than 1 in 10,000 patients.

Unknown: Cannot be estimated from the available data.

If any of the following occur, stop using MINOXIL FORTE and IMMEDIATELY notify your doctor or go to the emergency department of the nearest hospital:

Signs of sudden allergy; for example, swelling of hands, feet, ankles, face, lips, or especially swelling of the mouth or throat that makes swallowing or breathing difficult, skin rash (urticaria), sudden drop in blood pressure (hypotension), chest pain.

These are all very serious side effects. If you have any of these, it means you have a serious allergy to MINOXIL FORTE. You may need urgent medical intervention or hospitalization.

If you notice any of the following, immediately inform your doctor or consult the emergency department of the nearest hospital or your doctor:

Chest pain (Angina).

Changes in your heartbeat (acceleration or slowing).

Difficulty breathing (especially when lying down).

Unexplained rapid weight gain.

Urinating less than before.

Allergic reactions such as facial swelling, skin redness or itching, or a choking sensation.

Low blood pressure.

Rapid heartbeat or awareness of heartbeat (palpitations).

Fainting or dizziness.

Swelling in hands or feet, shortness of breath.

Sudden unexplained weight gain.

Persistent localized redness or rash.

These are all serious side effects. Urgent medical intervention may be required. Serious side effects are very rare.

If you notice any of the following, tell your doctor:

These side effects are listed by frequency of occurrence.

Very common

Headache.

Common

Hypersensitivity reactions.

Itching (including general itchy rash and eye itching).

Rash.

Eczema (dermatitis).

Unwanted hair growth outside the scalp has been reported (including facial hair growth in women). Always wash your hands thoroughly after application and rinse thoroughly with plenty of water if the solution accidentally gets on body areas other than your scalp.

Weight gain.

Facial edema.

Generalized redness, general itching.

Swelling of the face and a choking sensation in the throat.

Body edema.

Chest pain.

Uncommon

Nausea.

Dizziness.

Palpitations.

Difficulty breathing.

Rare

Changes in hair texture may occur. In such a case, you should stop using MINOXIL FORTE.

Unknown

Lip edema, lip swelling, mouth edema, throat swelling, tongue swelling and tongue edema (angioedema).

Increased heart rate.

Low blood pressure (hypotension).

Depression.

Eye irritation.

Vomiting.

All scalp irritations such as local redness, dryness, flaky skin have been reported. This may be due to the propylene glycol in the product. This is usually only a temporary effect, but if it persists, you should stop using this product.

Acne-like rash, itchy rash, blistering, bleeding or ulceration.

Temporary hair loss may occur in the first 2-6 weeks of use. This is likely the result of a change in the growth cycle and should stop within a few weeks. If this hair loss lasts longer than two weeks, stop using the product and talk to your doctor.

Changes in hair color may occur. In such a case, you should stop using Minoxil Forte Spray.

Skin dryness.

Flaking.

Skin irritation and burning.

Eczema.

Crusting.

Reactions at the application site (sometimes including areas close to the application site such as the ear and face). Typically, rashes such as itching, irritation, pain, redness, edema, dry skin may occur, but sometimes they can be more severe and flaking, eczema, blistering, bleeding and ulceration may be seen.

These are mild side effects of MINOXIL FORTE.

If you encounter any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you experience any side effects, whether listed in this leaflet or not, talk to your doctor, pharmacist or nurse. You can also report side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on www.titck.gov.tr or by calling the side effect notification line at 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

How to store MINOXIL FORTE?

Keep MINOXIL FORTE out of the sight and reach of children and in its packaging.

Store at room temperature below 25°C, in a dry place and protected from light.

Keep away from excessive heat and fire.

Use in accordance with the expiry date.

Do not use MINOXIL FORTE after the expiry date on the packaging.

"Do not throw away expired or unused medicines! Hand them over to the collection system determined by the Ministry of Environment, Urbanization and Climate Change."

Marketing Authorization Holder:

Humanis Sağlık A.Ş. Maslak/Sarıyer/İstanbul

Manufacturer:

Humanis Sağlık A.Ş. Kapaklı/Tekirdağ

This patient information leaflet was approved on