

## **Package Leaflet: Information for the user**

### **Minoxidil NET Forte 50 mg/ml cutaneous solution**

minoxidil

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

Always use this medication exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist, if you need more information or advice.  
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.
- You must talk to a doctor if your symptoms worsen or do not improve within 4 months.

#### **What is in this leaflet:**

1. What Minoxidil NET Forte is and what it is used for
2. What you need to know before you use Minoxidil NET Forte
3. How to use Minoxidil NET Forte
4. Possible side effects
5. How to store Minoxidil NET Forte
6. Contents of the pack and other information

#### **1. What Minoxidil NET Forte is and what it is used for**

Minoxidil Net Forte contains the active substance minoxidil, which stimulates hair growth. Minoxidil Net Forte is used for the treatment of early and less pronounced forms of hereditary hair loss (androgenetic alopecia) in men over 18 years and also to reduce further hair loss.

Minoxidil Net Forte is used to treat hair loss or thinning hair on the crown. The exact mechanism of action of minoxidil is not fully known. Younger persons who have lost hair for a brief period or exhibit small areas of skin where hair has become thinner have the best preconditions for effective treatment with Minoxidil Net Forte. Those who have had extensive bald areas for many years or have advanced hair loss are less likely to experience effect from the treatment. Hair loss can be delayed in about 4 out of 5 men, and most people using Minoxidil Net Forte also see some form of hair regrowth. An effect from the treatment can be expected after 2–4 months, in some cases, shorter or longer.

#### **2. What you need to know before you use Minoxidil NET Forte**

##### **Do not use Minoxidil Net Forte**

- if you are allergic to minoxidil or any of the other ingredients in this medicine (listed in Section 6).

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Minoxidil Net Forte

- if you have heart disease, including abnormal heart rhythm or heart rate, angina or chest pain, and/or circulatory disorders.

Minoxidil Net Forte should not be used for suddenly occurring or patchy hair loss or if the skin or scalp is red, inflamed, irritated, infected or sore.

Stop using Minoxidil Net Forte and contact a doctor if any of the following symptoms occur:

- Chest pain.
- Rapid heart rate (pulse)
- Dizziness and/or a tendency to faint
- Sudden, unexplained weight gain
- Swollen hands and feet
- Persistent redness and irritation of the scalp in the places treated.
- Swollen face, tongue or throat
- Difficulty in swallowing
- Hives and difficulty breathing
- Other unexpected new symptoms

You should not use Minoxidil Net Forte

- If the pattern of your hair loss is not characterized by a receding hairline and/or thinning hair on the crown
- If hair loss has never affected anyone else in your family
- If your hair loss is sudden or patchy
- If you do not know the cause of the hair loss
- If you have a red, inflamed, irritated or painful scalp

Avoid contact with your eyes, mouth and other mucous membranes and skin lesions.

Because Minoxidil Net Forte contains alcohol (ethanol) it is very flammable.

Using more than the recommended dose or a more frequent use will not improve results.

Continued use is necessary to increase and maintain hair regrowth, otherwise the hair loss will return.

At the beginning of the treatment, that is after 2–6 weeks, a temporary increase in hair loss may occur. If the hair loss continues for more than two weeks, you should stop the treatment.

Accidental ingestion of Minoxidil Net Forte may cause serious cardiovascular side effects. Therefore, this product must be kept out of reach of children.

To reduce the risk of unwanted hair growth, you should ensure that Minoxidil Net Forte is only applied to the scalp and wash your hands thoroughly every time you have used Minoxidil Net Forte (see section 4, Possible side effects).

Cases of excessive hair growth on the body of infants have been reported following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hair growth returned to normal within months when infants were no longer exposed to minoxidil. Care should be taken to ensure that children do not come into contact with areas of your body where you have applied minoxidil topically.

Consult a doctor if you notice excessive hair growth on the body of your child during the period you are using topical minoxidil products.

### **Children and adolescents**

Minoxidil Net Forte is not recommended for use in children and adolescents below 18 years of age. There is no information about the safety and efficacy for people under 18 years.

### **Other medicines and Minoxidil NET Forte**

Minoxidil Net Forte should not be used together with other medicines that are applied to the scalp. Tell your doctor if you are using other medicines applied to the skin, such as tretinoin, dithranol or betamethasone. These medicines can cause the skin to absorb greater or lesser amounts of minoxidil

(the active ingredient in Minoxidil Net Forte).

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### **Pregnancy and breast-feeding**

Minoxidil Net Forte should not be used by women.

### **Driving and using machines**

Minoxidil Net Forte may cause dizziness or low blood pressure. If you experience these side effects, do not drive or use machines.

### **Minoxidil NET Forte contains propylene glycol and alcohol (ethanol)**

This medicine contains 550 mg propylene glycol per ml and 0.3 ml alcohol (ethanol) per ml. Ethanol may cause burning sensation on damaged skin.

## **3. How you use Minoxidil NET Forte**

Always use this medication exactly as described in this leaflet or as directed by your doctor, pharmacist or nurse. Check with your doctor, pharmacist or nurse if you are not sure.

### Directions for use

The hair and scalp must be completely dry before applying Minoxidil Net Forte.

Apply and distribute 1 ml solution twice a day (morning and evening) on the scalp area/areas of hair loss. 1 ml corresponds to 6 pump actuations of spray. Do not use more than 1 ml per application and not more often than twice a day (more frequent application does not accelerate the effect). For optimal effect use Minoxidil Net Forte every day. Continued use is necessary to increase and maintain hair regrowth, otherwise the hair loss will return.

Prior to initial use, the pump must be assembled. Remove the bottle's screw cap and screw on the spray pump firmly. Next, put the spray nozzle onto the spray pump and press it a few times to produce a uniform spray.

1. Distribute the 6 pump actuations of spray (equivalent to 1 ml) over the surfaces to be treated (morning and evening).
2. Spread and lightly massage Minoxidil Net Forte into the scalp using your fingertips over the surfaces to be treated.
3. Wash hands thoroughly afterwards.

Minoxidil Net Forte contains alcohol which may cause burning sensation on damaged skin. Rinse thoroughly with cold water if Minoxidil Net Forte should happen to come in contact with eyes, mouth or sores on the skin.

Do not inhale the sprayed solution.

In order not to interfere with the effectiveness of Minoxidil Net Forte, you should use a silicone-free shampoo when washing your hair (silicone may also be named dimethicone).

### **Duration of treatment**

Since hair growth is a slow process Minoxidil Net Forte requires some time in order to work. Usually it requires continuous use twice a day for at least two months before the effect becomes noticeable. In some cases, it may take longer. If no effect is seen after 4 months treatment should be discontinued. Tell your doctor if your symptoms worsen or do not improve within 4 months.

### **If you have used more Minoxidil NET Forte than you should**

If used incorrectly or if you have an over-sensitivity, there may be a risk of side effects due to increased absorption through the skin. In the case of accidental oral intake, the most likely signs of overdose of Minoxidil Net Forte are effects on the heart and blood vessels in the form of increased heart rate (pulse), low blood pressure and abnormal fatigue. Contact a doctor if you experience these symptoms – you may need medical attention.

**If you forget to use Minoxidil NET Forte**

Do not use a double dose to make up for the forgotten dose. Resume treatment as described in section 3 “How you use Minoxidil Net Forte”.

**If you stop using Minoxidil NET Forte**

If the treatment is discontinued, the effect ceases within 3 to 4 months and the hair loss will return.

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

**4. Possible side effects**

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

At the beginning of the treatment, that is after 2–6 weeks, a temporary increase in hair loss can occur. This is caused by hair follicles undergoing change from a dormant state (old hair) to an active growing phase (new hair). When this new growth starts, old hair detaches from the scalp, which is perceived as hair loss. If the hair loss continues for more than 2 weeks, you should stop the treatment and contact your doctor.

**Stop using Minoxidil Net Forte and immediately contact a doctor if you experience any of the following symptoms – you may need urgent medical attention.**

- Swelling of the face, lips or throat, difficulty in swallowing, hives and breathing difficulties. This can be a sign of a severe allergic reaction (frequency not known, cannot be estimated from the available data).
- Palpitations, dizziness or fainting.

**Other side effects that may occur:**

*Very common (may affect more than 1 in 10 people):*  
Headache.

*Common (may affect up to 1 in 10 people):*

During treatment, some skin irritation may occur. This effect, caused by the alcohols (ethanol and propylene glycol) in the solution, is usually temporary. If it turns out that this is not the case, the treatment should be discontinued. If you accidentally get Minoxidil Net Forte in the eyes, mouth or damaged skin, it is most easily dispersed by rinsing with plenty of cold water. Shortness of breath and swelling of hands and feet, skin inflammation, itching, rash, weight gain and unwanted hair growth (in places other than the scalp).

*Uncommon (may affect up to 1 in 100 people):*  
Dizziness, nausea.

*Rare (may affect up to 1 in 1,000 people):*

Palpitations, increased heart rate, chest pain, folliculitis.

*Not known (frequency cannot be estimated from the available data):*

Low blood pressure. Hypersensitivity, allergic contact dermatitis, eye irritation, vomiting.

Reactions at the site of treatment that may include itching, irritation, pain, rash, swelling, dry skin and

redness of the scalp, ears or face. The reactions can sometimes be more serious and include flaky skin, skin inflammation, blistering, bleeding and ulceration.  
Temporary hair loss, changes in hair colour and hair texture.

### **Reporting of side effects**

If you get any side effects, talk with a doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help to provide more information on the safety of this medicine.

## **5. How to store Minoxidil NET Forte**

Keep this medicine out of the sight and reach of children.

The bottle contains highly flammable liquid and should be tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Do not throw away the medicine via wastewater or in household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Minoxidil NET Forte contains**

- The active substance is minoxidil 50 mg/ml
- The other ingredients are propylene glycol, ethanol and water.

### **What Minoxidil NET Forte looks like and contents of the pack**

Minoxidil Net Forte is a clear, colourless/yellowish solution in a plastic bottle. A spray pump with an extended spray nozzle is included in the package.

Minoxidil Net Forte comes in packs of 60 ml, 2x60 ml and 3x60 ml.

Not all pack sizes may be marketed.

### **Market Authorisation Holder**

[To be completed nationally]

### **Manufacturer**

[To be completed nationally]

### **This leaflet was last revised in**

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