SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Minoxidil NET Forte 50 mg/ml cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 50 mg of minoxidil.

Excipients with known effect:
Ethanol 96% 0.30 ml
Propylene glycol 550 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous solution.
Clear, colourless/yellowish solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the stimulation of hair growth in early and less pronounced forms of androgenetic alopecia as well as to reduce further hair loss in adult men.

4.2 Posology and method of administration

Minoxidil Net Forte is intended for men aged 18 and above.

Posology
1 ml applied twice daily (once in the morning and once in the evening) on the area of skin to be treated. 6 pump actuations from the spray pump correspond to 1 ml. This dose should be used regardless of the size of the skin area, or even if several areas are to be treated simultaneously.

Method of administration
For external use only. Minoxidil Net Forte should be used only as directed and should not be applied to other areas of the skin than prescribed. Both the hair and the scalp should be completely dry before Minoxidil Net Forte is applied. Place the pump nozzle on the bottle and distribute 6 pump actuations from the spray pump, which is equivalent to 1 ml, over the surfaces to be treated. After application, always massage the scalp lightly with the fingertips. Hands should be washed thoroughly after application. Avoid breathing vapours.

In order not to interfere with the absorption of minoxidil, a silicone-free shampoo should be used when washing the hair (silicone may also be named dimethicone).

Do not use more than 2 ml per day and apply not more often than twice a day (more frequent application does not accelerate the effect). One or two forgotten applications is without significance. Treatment should be resumed in the prescribed manner.

It may require two applications daily for at least 2 to 4 months for the effect to become noticeable. If no improvement is seen after 4 months, the treatment should be discontinued.

Special populations
There are no specific recommendations for use in elderly patients or in patients with renal or hepatic impairment.

Paediatric population
Minoxidil Net Forte is not recommended for use in children below the age of 18 years due to a lack of data on safety and efficacy.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

Minoxidil for topical application should only be used on a normal, healthy scalp, which is not inflamed, infected, irritated or painful.

Minoxidil is not indicated for hair loss that is not hereditary, or in sudden hair loss and/or patchy hair loss or of unknown genesis.

For precautionary reasons, people with known cardiovascular disease, or cardiac arrhythmia should consult a doctor before starting treatment.

Treatment should be discontinued and a doctor contacted in the event of chest pain, increased heart rate, dizziness or fainting, sudden weight gain without apparent cause or swelling in the hands and feet. Discontinue treatment in the event of persistent redness or other signs of irritation of the scalp, or if other unexpected, new symptoms occur (see section 4.8).

Topical minoxidil should not be used concurrently with other medicinal products applied to the scalp.
Using more than the recommended dose or more frequent applications will not improve results. Continued use is necessary to increase and maintain hair regrowth, otherwise hair loss will resume.
Unwanted hair growth may be caused if the product comes in contact with other areas of the skin than the scalp.
Hypertrichosis in children following inadvertent topical exposure to minoxidil:
Cases of hypertrichosis have been reported in infants following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hypertrichosis was

reversible, within months, when infants were no longer exposed to minoxidil. Contact between children and minoxidil application sites should therefore be avoided.

In some cases, an increased shedding of hair has been reported at the start of minoxidil treatment. This is likely due to minoxidil's action of shifting hairs in the resting telogen phase to the growing anagen phase (old hair being pushed out by new hair growing in its place). This temporary increase in hair loss usually occurs 2–6 weeks after the initiation of treatment and ceases within a couple of weeks. If the hair rejection continues for more than two weeks, treatment should be discontinued and the doctor contacted.

Despite the extensive experience with topical application of minoxidil, no evidence has been seen that the absorption of adequate amounts of minoxidil causes systemic effects. However, at least theoretically, the absorption of large quantities due to misuse or exceptional sensitivity, might lead to a systemic effect, something that the person using the product should be aware of.

Minoxidil Net Forte contains propylene glycol and ethanol (alcohol). Ethanol may cause burning sensation on damaged skin. In case of accidental contact with sensitive areas (eyes, wounds and mucous membranes) the area should be rinsed with copious amounts of cool tap water.

Inhalation of sprayed solution should be avoided.

Paediatric population
There is no information about the safety and efficacy for people under 18 years.

Accidental ingestion may cause serious cardiac adverse reactions. Therefore, this product must be kept out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no currently known interactions following simultaneous administration of systemically acting medicinal products and topical application of minoxidil.

Topical minoxidil should not be used concurrently with other medicinal products applied to the scalp. The absorption of topically applied minoxidil is inhibited and limited by the barrier formed by the stratum corneum.

Topically applied substances such as tretinoin and dithranol that do affect this barrier can, if used concomitantly, result in an increased absorption of topically applied minoxidil.

Corticoid betamethasone may reduce the absorption of minoxidil, when concomitantly topically applied.

4.6 Fertility, pregnancy and lactation

Minoxidil Net Forte should not be used by women.

4.7 Effects on ability to drive and use machines

Minoxidil may cause dizziness and hypotension. Patients experiencing these adverse reactions should not drive or use machines.

4.8 Undesirable effects

The safety of topical minoxidil from clinical trials is based on the data from 7 placebo-controlled randomised clinical trials conducted in adults where either 2% or 5% minoxidil solution was evaluated and two placebo-controlled randomised clinical trials in adults, where a 5% foam formulation was evaluated.

The table below shows the adverse reactions that have been reported for minoxidil from clinical trials and from post-marketing experience, divided into system organ class.
The following frequency categories have been used:

Very common (≥ 1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000) and Very rare (<1/10,000), not known (cannot be estimated from available data).

Frequency categories for the events are based on 1) the incidence in well-designed clinical trials or epidemiological studies where available, or 2) when the incidence cannot be calculated the frequency category “not known” is assigned.

System Organ Class	**Frequency**	**Reported adverse reactions**
Infections and infestations	Rare	Folliculitis
Immune system disorders	Not known	Allergic reactions, including angioedema Allergic contact dermatitis Hypersensitivity
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
Eye disorders	Not known	Eye irritation
Cardiac disorders	Rare	Chest pain Palpitations Increased heart rate (tachycardia)
Vascular disorders	Not known	Hypotension
Respiratory, thoracic, and mediastinal disorders	Common	Dyspnoea
Gastrointestinal disorders	Uncommon	Nausea
	Not known	Vomiting
Skin and subcutaneous tissue disorders	Common	Dermatitis (including seborrheic dermatitis) Dermatitis acneiform Hypertrichosis (undesired hair growth in other places than in scalp, including facial hair growth in women) Pruritus Rash

System Organ Class	Frequency	Reported adverse reactions
	Not known	Change in hair colour Change in hair texture Temporary hair loss
General disorders and administration site conditions	Common	Peripheral oedema
	Not known	Application site reactions (these may sometimes involve surrounding structures such as the ears and face and usually consist of itching, irritation, pain, rash, oedema, skin dryness and erythema but can sometimes be more severe and include exfoliation, dermatitis, blisters, bleeding and ulceration).
Investigations	Common	Weight gain*

* This adverse reaction was identified in clinical trials on minoxidil foam.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction via the national reporting system listed in Appendix V.

4.9 Overdose

Increased systemic absorption of minoxidil may potentially occur if larger than recommended doses are applied to large body areas or areas other than the scalp, which therefore can lead to adverse reactions.

Due to the minoxidil concentration in Minoxidil Net Forte, accidental ingestion has the potential of producing systemic effects. These are related to the pharmacological action of the medicinal product (2 mL Minoxidil Net Forte contains 100 mg minoxidil, which is the maximum recommended adult dose of orally administered minoxidil in the treatment of hypertension). Signs and symptoms of minoxidil overdose would primarily be cardiovascular effects associated with sodium and water retention. Tachycardia, hypotension and lethargy may also occur.

Treatment: In case of minoxidil overdose, the treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatologicals, including medical shampoos. ATC code: D11AX01

Minoxidil is a piperidine-pyrimidine derivative. The exact mechanism of action of minoxidil in the treatment of androgenetic alopecia is not known, however minoxidil can stop hair loss and stimulate regrowth in androgenetic alopecia by the following means:

- Increasing the diameter of the hair shaft.

- Stimulating anagen growth.
- Prolongation of the anagen phase.
- Stimulation of reversion to the anagen phase from the telogen phase.

Moderate clinical effect has been shown on the vertex. No studies of the effect on the receding hairline on the temples have been carried out. Typically, reduced hair loss is achieved first. Two applications daily for 2–4 months, in some cases for a shorter or longer period of time, is required to get a visible effect. Both the degree of hair growth and how quickly this occurs varies individually. In about 4 out of 5 men additional hair loss ceases. A return to the original condition has been reported to occur 3–4 months after treatment has ended. Orally administered minoxidil in higher doses has a peripheral vasodilator effect, which reduces the elevated systolic and diastolic blood pressure by reducing peripheral resistance in blood vessels.

5.2 Pharmacokinetic properties

Following topical application of Minoxidil Net Forte, minoxidil is absorbed to a small degree of normal intact skin. On average 1.4% (range: 0.3–4.5%) of the total dose enters systemic circulation compared with oral administration of minoxidil. The effect on the absorption in concomitant skin disease is unknown.

Following withdrawal of topical treatment with Minoxidil Net Forte, 95% of systemically absorbed minoxidil is eliminated within 4 days. The metabolism of topically applied minoxidil is not known in detail.

Minoxidil does not bind to plasma proteins, and its renal clearance corresponds to the GFR. Minoxidil and its metabolites can be haemodialyzed and is excreted, primarily via the urine.

5.3 Preclinical safety data

Preclinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

Teratogenicity
Animal studies of reproductive toxicity in rats and rabbits have shown signs of maternal toxicity and a risk to the foetus at exposure levels that are very high compared to the levels reached in humans for intended use (a 19- to 570-fold higher exposure than in humans).

Fertility
In rats, minoxidil doses greater than 9 mg/kg (at least 25-fold human exposure) administered subcutaneously, was associated with reduced conception and implantation rates as well as a reduction in the number of live pups.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol

Propylene glycol
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

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 30ºC.

6.5 Nature and contents of container

60 ml, 2x60 ml and 3x60 ml HDPE bottle with polypropylene screw cap. A spray pump with an extended spray nozzle is included in the package.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special instructions.

7. MARKET AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

15 November 2024