LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Minoxidil NET Forte
(minoxidil)

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Cutaneous solution, 50 mg/ml

This is a summary of the public assessment report (PAR) for Minoxidil NET Forte. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Minoxidil NET Forte and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The reference medicine for the product is Rogaine.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

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.

How does Minoxidil NET Forte work?

Minoxidil Net Forte contains the active substance minoxidil, which stimulates hair growth. 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.

How is Minoxidil NET Forte used?

The pharmaceutical form is cutaneous solution for cutaneous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can be obtained without a prescription in Sweden.

What benefits of Minoxidil NET Forte have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Rogaine, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Minoxidil NET Forte?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Minoxidil NET Forte approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and therapeutically equivalent to the reference medicine Rogaine. Therefore, the Swedish Medical Products Agency decided that, as for Rogaine, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Minoxidil NET Forte?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Minoxidil NET Forte

The full PAR for Minoxidil NET Forte can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Minoxidil NET Forte, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-08.