

Summary Public Assessment Report

Rogaine (minoxidil)

SE/H/1173/01/E01

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Rogaine
(minoxidil)

cutaneous foam, 50 mg/g

This is a summary of the public assessment report (PAR) for Rogaine. It explains how Rogaine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Rogaine.

For practical information about using Rogaine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rogaine and what is it used for?

Rogaine is used in the treatment of men with common hereditary hair loss (also called androgenetic alopecia). It is to be used only on the scalp (head).

How does Rogaine work?

Rogaine contains minoxidil. Minoxidil regrows hair and stabilizes hair loss in men with a receding hairline and crown balding by revitalization of hair follicles.

How is Rogaine used?

The pharmaceutical form of Rogaine is cutaneous foam be used only on the scalp (head).

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.

What benefits of Rogaine have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Rogaine is effective in treating of men with common hereditary hair loss.

What are the possible side effects of Rogaine?

For the full list of all side effects reported with Rogaine, see section 4 of the package leaflet.

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

Why is Rogaine approved?

It was noted that the effect of Rogaine in the treatment of of men with common hereditary hair loss was significantly better than treatment with placebo. Therefore, the Medical Products

Agency in Sweden decided that Rogaine's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Rogaine?

A risk management plan has been developed to ensure that Rogaine 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 for Rogaine, 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 Rogaine

The marketing authorisation for Rogaine was granted on 2012-11-01 in Sweden.

The full PAR for Rogaine can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Rogaine, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-01.