LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Roquinna 50 mg/g, cutaneous foam

Minoxidil

SE/H/1503/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Roquinna
Minoxidil

cutaneous foam, 50 mg/g

This is a summary of the public assessment report (PAR) for Roquinna . It explains how Roquinna 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 Roquinna .

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

What is Roquinna and what is it used for?
Roquinna is used to treat women with common hereditary thinning or hair loss in the parting (also called androgenetic alopecia, female type)

How does Roquinna work?
Roquinna contains minoxidil. Minoxidil regrows hair in women by revitalization of hair follicles.

How is Roquinna used?

The pharmaceutical form of Roquinna is cutaneous foam for use on the scalp only.

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 Roquinna have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Roquinna is effective in treating female pattern hair loss.

What are the possible side effects of Roquinna ?

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

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

Why is Roquinna approved?

It was noted that the effect of Roquinna in the treatment of female pattern hair loss was significantly better than treatment with placebo, while a similar effect was obtained with Roquinna when compared to a solution containing minoxidil. The risk with Roquinna is comparable to the risks with a minoxidil solution. Roquinna does not contain propylene

glycol as the solution does, which may lead to less skin irritation in treated areas. Therefore, the Medical Products Agency in Sweden decided that Roquinna ’s benefits are greater than its risks and recommended that it could be approved for use.

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

A risk management plan has been developed to ensure that Roquinna 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 Roquinna , 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 Roquinna

The marketing authorisation for Roquinna was granted on 2016-04-14 in Sweden.

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

This summary was last updated in 2016-04-14.