LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Soolantra
(ivermectin)

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Summary Public Assessment Report

Soolantra

(ivermectin)

Cream, 10mg/g

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

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

What is Soolantra and what is it used for?
Soolantra contains the active substance ivermectin that belongs to a group of medicines called avermectins. The cream is used on the skin to treat pimples and spots found with rosacea.

How does Soolantra work?
Ivermectin is a member of the avermectin class. Avermectin has anti-inflammatory effects. Ivermectin also causes death of parasites, Demodex mites, that have been reported to be a factor in inflammation of the skin.

How is Soolantra used?
The pharmaceutical form of Soolantra is cream for topical 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 only be obtained with a prescription.

What benefits of Soolantra have been shown in studies?
The company provided its own data on efficacy and safety studies. These studies have shown that Soolantra is effective in topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.

What are the possible side effects of Soolantra?
For the full list of all side effects reported with Soolantra, see section 4 of the package leaflet.

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

Why is Soolantra approved?
It was noted that the effect of Soolantra in the treatment of inflammatory lesions of rosacea (papulopustular) in adult patients was significantly better than treatment with placebo (multicenter, randomized, double-blind, vehicle-controlled studies). Therefore, the Medical Products Agency in Sweden decided that Soolantra'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 Soolantra?
A risk management plan has been developed to ensure that Soolantra 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 Soolantra, 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 Soolantra
The marketing authorisation for Soolantra was granted on 2015-04-22 in Sweden.

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

This summary was last updated in 2015-05.