LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Cesora
(ivermectin)

SE/H/2398/01/DC

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Summary Public Assessment Report

Cesora
ivermectin

Cream, 10 mg/g

This is a summary of the public assessment report (PAR) for Cesora. 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 Cesora 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 Soolantra.

Cesora should be used in adults only (18 years of age or older).

How does Cesora work?

Cesora 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 is Cesora used?

The pharmaceutical form 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 in Sweden.

What benefits of Cesora have been shown in studies?

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

What are the possible side effects from Cesora?

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 Cesora approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is similar to the reference medicine. Therefore, the Swedish Medical Products

Agency decided that, as for Soolantra, 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 Cesora?

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.

For more details, please see the full PAR for Cesora on the following website: MRI - Home.

Other information about Cesora

The full PAR for Cesora can be found on the following website: MRI - Home. For more information about treatment with Cesora, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-01.