LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Betametason/Salicylsyra Orifarm (betamethasone dipropionate, salicylic acid)

SE/H/2255/01/DC

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Summary Public Assessment Report

Betametason/Salicylsyra Orifarm
betamethasone dipropionate, salicylic acid

Ointment, 0,5 mg/g + 30 mg/g

This is a summary of the public assessment report (PAR) for Betametason/Salicylsyra Orifarm. 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 Betametason/Salicylsyra Orifarm 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 Diprosalic.

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

The product is used for psoriasis and other dry and scaly skin diseases in adults and children.

How does Betametason/Salicylsyra Orifarm work?

The product contains the active substances betamethasone and salicylic acid. Betamethasone reduce inflammation and has effect on allergic and itchy skin diseases. Salicylic acid is a substance that softens the skin.

How is Betametason/Salicylsyra Orifarm used?

The pharmaceutical form is an ointment for external 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 Betametason/Salicylsyra Orifarm have been shown in studies?

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

What are the possible side effects from Betametason/Salicylsyra Orifarm?

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 Betametason/Salicylsyra Orifarm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Dirposalic, 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 Betametason/Salicylsyra Orifarm?

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 Betametason/Salicylsyra Orifarm

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

This summary was last updated in 2023-05.