LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ovixan
(mometasone furoate)

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Summary Public Assessment Report

Ovixan

(mometasone furoate)

Cutaneous solution; 1 mg/g

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

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

What is Ovixan and what is it used for?
Ovixan is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The reference medicine for Ovixan is Elocon.

Adults and children above 6 years:
Ovixan has an anti-inflammatory effect and reduces itchiness. Ovixan is used to decrease symptoms in connection with e. g. psoriasis, eczema and other skin diseases that can be treated with a corticosteroid. It does not cure your skin disease, but it relieves your symptoms.

How does Ovixan work?
Ovixan contains the active substance mometasone furoate and it is a corticosteroid for cutaneous use. Corticosteroids for cutaneous use are divided into four classes depending on strength and effect: mild effect, medium effect, strong effect and very strong effect. Mometasone furoate belongs to the class "corticosteroid with strong effect".

How is Ovixan used?
The pharmaceutical form of Ovixan is cutaneous solution for cutaneous (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.

What benefits of Ovixan have been shown in studies?
Because Ovixan is a hybrid application and is considered to be therapeutically equivalent, to the reference product Elocon, their benefits and risks are taken as being the same as those of the reference medicine.

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

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

Why is Ovixan approved?
This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical

Products Agency in Sweden decided that Ovixan'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 Ovixan?
A risk management plan has been developed to ensure that Ovixan 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 Ovixan, 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 Ovixan
The marketing authorisation for Ovixan was granted on 2012-11-16 in Sweden.

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

This summary was last updated in 2015-01.