COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

non-generics

Mometasonfuroaat Sandoz 1 mg/g, cream

(mometasone furoate)

NL/H/4297/001/DC

Date: 27 June 2018

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Active substance: mometasone furoate

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

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

What is Mometasone Sandoz and what is it used for?
Mometasonfuroaat Sandoz is a 'hybrid generic medicine'. This means that it is similar to a reference medicine Elocon containing the same active substance, but the active substance mometasone furoate has a local effect, on the skin, and is not absorbed by the body. Therefore, the amount is not measurable in the blood to directly compare Mometasonfuroaat Sandoz with Elocon. When this is the case, the term 'hybrid' is used.

In adults and children, aged 2 years and over, this medicine is used to reduce symptoms caused by certain inflammatory skin disorders such as psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis. This preparation is generally used to treat very dry, scaly and cracked skin complaints. It is not a cure for the condition, but should help to relieve symptoms.

How does this medicine work?
Mometasonfuroaat Sandoz contains the active substance mometasone furoate, which belongs to a group of medicines called topical corticosteroids (or steroids). Topical corticosteroids can be divided into four degrees of strength or potency: mild, moderate, potent and very potent. This medicine is classified as a "potent corticosteroid".

How is this medicine used?
The pharmaceutical form of Mometasonfuroaat Sandoz is a cream and the route of administration is cutaneous (use on the skin). This medicine is for external use only.

The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Mometasonfuroaat Sandoz 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 from this medicine?
Side effects with Mometasonfuroaat Sandoz (uncommon, which may affect up to 1 in 100 people) are skin dryness, inflamed skin (dermatitis), softening and whitening of the skin (maceration) and heat rash/prickly heat (miliaria).

Why is this medicine approved?
The Medicines Evaluation Board decided that Mometasonfuroaat Sandoz'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 Mometasonfuroaat Sandoz?
A risk management plan has been developed to ensure that Mometasonfuroaat Sandoz 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 Mometasonfuroaat Sandoz, 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 Mometasonfuroaat Sandoz
The marketing authorisation for Mometasonfuroaat Sandoz was granted on 3 July 2015.

The full PAR for Mometasonfuroaat Sandoz can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Mometasonfuroaat Sandoz, read the package leaflet (http://mri.cts-mrp.eu/Human/Product/Details/44281) or contact your doctor or pharmacist.

This summary was last updated in June 2018.