Summary Public Assessment Report

Fusidinsyre/betamethasonvalerat “Leo”

Fusidic acid and betamethasone (as valerate)

DK/H/2355/001/DC

9 October 2015

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Fusidinsyre/betamethasonvalerat “Leo”

Fusidic acid 20 mg/g and betamethasone as betamethasone valerate 1 mg/g cream

This is a summary of the public assessment report (PAR) for Fusidinsyre/betamethasonvalerat “Leo”. It explains how Fusidinsyre/betamethasonvalerat “Leo” 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 Fusidinsyre/betamethasonvalerat “Leo”.

For practical information about using Fusidinsyre/betamethasonvalerat “Leo”, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fusidinsyre/betamethasonvalerat “Leo” and what is it used for?
Fusidinsyre/betamethasonvalerat “Leo” is a ‘generic medicine’. This means that Fusidinsyre/betamethasonvalerat “Leo” is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Fucicort Lipid cream.
Fusidinsyre/betamethasonvalerat “Leo” is used in the treatment of skin disorders where infections are caused by bacteria which are sensitive to fusidic acid.

How does Fusidinsyre/betamethasonvalerat “Leo” work?
Fusidinsyre/betamethasonvalerat “Leo” cream contains two different types of medicine. One medicine is an antibiotic (fusidic acid) and the other medicine is a corticosteroid (betamethasone valerate). Fusidic acid works by halting the growth of bacteria and betamethasone works by reducing any inflammation and itchiness of the skin.

How is Fusidinsyre/betamethasonvalerat “Leo” used?
The pharmaceutical form of Fusidinsyre/betamethasonvalerat “Leo” is cream and the route of administration is cutaneous (for use on the skin).

Dosing for adults and children is a thin layer 2-3 times a day for up to 2 weeks.

Fusidinsyre/betamethasonvalerat “Leo” cream should only be used on inflamed skin. It is important to wash hands after every application of Fusidinsyre/betamethasonvalerat “Leo” cream unless the skin on the hands is being treated.

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 Fusidinsyre/betamethasonvalerat “Leo” have been shown in studies?
Fusidinsyre/betamethasonvalerat “Leo” is a generic medicine, that is identical to the reference medicine, Fucicort Lipid. Thus, the two medicines are considered bioequivalent. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Fusidinsyre/betamethasonvalerat “Leo”?
Because Fusidinsyre/betamethasonvalerat “Leo” is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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

Why is Fusidinsyre/betamethasonvalerat "Leo" approved?
It was concluded that, in accordance with EU requirements, Fusidinsyre/betamethasonvalerat "Leo" has been shown to have comparable quality and to be bioequivalent/be comparable to Fucicort Lipid. Therefore, the member states involved in the procedure concluded that, as for Fucicort Lipid, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Fusidinsyre/betamethasonvalerat "Leo"?
A risk management plan has been developed to ensure that Fusidinsyre/betamethasonvalerat "Leo" 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 Fusidinsyre/betamethasonvalerat "Leo", 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 Fusidinsyre/betamethasonvalerat "Leo".
The marketing authorisation for Fusidinsyre/betamethasonvalerat "Leo" was granted on 25 March 2015.

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

This summary was last updated in 10-2015.