LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nystimex
(nystatin)

SE/H/1366/01/DC

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Summary Public Assessment Report

Nystimex

(nystatin)

Oral suspension; 100 000 IU/ml

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

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

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

Nystimex is used to treat fungal infections in the mouth and intestines.

How does Nystimex work?
Nystimex belongs to the group of antifungal medicines. It contains the active ingredient nystatin. It has a local effect on the mucosa and is not absorbed into the body.

How is Nystimex used?
The pharmaceutical form of Nystimex is oral suspension for oral 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 Nystimex have been shown in studies?
Because Nystimex is a hybrid application and is considered to be therapeutically equivalent, to the reference product Mycostatin, their benefits and risks are taken as being the same as those of the reference medicine.

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

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

Why is Nystimex 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 Nystimex'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 Nystimex?
A risk management plan has been developed to ensure that Nystimex 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 Nystimex, 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 Nystimex
The marketing authorisation for Nystimex was granted on 2015-02-12 in Sweden.

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

This summary was last updated in 2015-02.