LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nystatin Orifarm
(nystatin)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

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Nystatin Orifarm

(nystatin)

Oral suspension, 100 000 IU/ml

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

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

What is Nystatin Orifarm and what is it used for?

Nystatin Orifarm, is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Nystatin Orifarm is Mycostatin. Nystatin Orifarm is used to treat fungal infections in the mouth and intestines.

How does Nystatin Orifarm work?

Nystatin Orifarm 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 Nystatin Orifarm used?

The pharmaceutical form of Nystatin Orifarm 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 Nystatin Orifarm have been shown in studies?

Because Nystatin Orifarm 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 Nystatin Orifarm?

For the full list of all side effects reported with Nystatin Orifarm, see section 4 of the package leaflet.

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

Why is Nystatin Orifarm approved?

Since this medicine is the same as Mycostatin, which is already authorised, no new or unexpected safety concerns arose from this application. Therefore, the Medical Products Agency in Sweden decided that Nystatin Orifarm'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 Nystatin Orifarm?

A risk management plan has been developed to ensure that Nystatin Orifarm 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 Nystatin Orifarm, 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 Nystatin Orifarm

The marketing authorisation for Nystatin Orifarm was granted on 2018-03-26 in Sweden.

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

This summary was last updated in 2018-06.