



# **Public Assessment Report**

## **National Procedure**

**Nystatin 100,000 units/ml Oral Suspension**

**nystatin**

**PL 47587/0011**

**Vygoris Limited**

## LAY SUMMARY

### Nystatin 100,000 units/ml Oral Suspension nystatin

This is a summary of the Public Assessment Report (PAR) for Nystatin 100,000 units/ml Oral Suspension. It explains how this product 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 this product.

This product will be referred to as Nystatin Oral Suspension in this lay summary for ease of reading.

For practical information about using Nystatin Oral Suspension, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

#### **What is Nystatin Oral Suspension and what is it used for?**

This application is the same as Nystan Oral Suspension, PL 47587/0005 which is already authorised.

The Company responsible for Nystan Oral Suspension, PL 47587/0005 has agreed that its scientific data can be used as the basis for the grant of an identical licence for Nystatin Oral Suspension.

Nystatin Oral Suspension is used to prevent and treat fungal infections (thrush) of the mouth, throat or gut. It also provides effective prevention against oral thrush in those born of mothers with vaginal thrush.

#### **How does Nystatin Oral Suspension work?**

This medicine contains nystatin as the active ingredient. Nystatin belongs to a group of medicines called anti-fungal antibiotics. This medicine works by killing the yeast or fungus that has caused the symptoms.

#### **How is Nystatin Oral Suspension used?**

The pharmaceutical form of this medicine is oral suspension and the route of administration is oral (by mouth).

The recommended dose for adults and children is 1 ml of suspension dropped into the mouth four times a day. In the case of newborn babies, the recommended dose is 1 ml once a day dropped into the mouth.

There are no specific dosage recommendations or precautions for older people.

Taking this medicine:

- Shake the bottle well before use.
- Use the measuring dropper provided, which is graduated in 0.5 ml steps.
- Doses should be equally spaced throughout the day.
- If the patient is taking this medicine for an infection in the mouth or throat, they should try not to swallow the suspension too quickly, as the longer the medicine is in contact with the site of infection the better.

The patient's doctor will normally have given sufficient medicine to enable the patient to continue treatment for 48 hours after all symptoms have disappeared. This will help to clear up the patient's infection completely and prevent a relapse. If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should talk to their doctor.

For further information on how Nystatin Oral Suspension is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

**What benefits of Nystatin Oral Suspension have been shown in studies?**

Nystatin Oral Suspension is considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Nystatin Oral Suspension, however, reference is made to the studies for Nystan Oral Suspension.

**What are the possible side effects of Nystatin Oral Suspension?**

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at <https://yellowcard.mhra.gov.uk> or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Nystatin Oral Suspension is considered to be identical to the previously authorised product with the same benefits and risks.

**Why was Nystatin Oral Suspension approved?**

The MHRA decided that the benefits of Nystatin Oral Suspension are greater than the risks and recommended that this medicine is approved for use.

**What measures are being taken to ensure the safe and effective use of Nystatin Oral Suspension?**

As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Nystatin Oral Suspension. The RMP details the important risks of Nystatin Oral Suspension, how these risks can be minimised, any uncertainties about Nystatin Oral Suspension (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Nystatin Oral Suspension.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Nystatin Oral Suspension are

continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

**Other information about Nystatin Oral Suspension**

A marketing authorisation was granted in the United Kingdom on 06 January 2023.

The full PAR for Nystatin Oral Suspension follows this summary.

This summary was last updated in March 2023.

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## I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Nystatin 100,000 units/ml Oral Suspension (PL 47587/0011) could be approved.

The product is approved for the following indications:

The prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract. The suspension provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

The name of the active substance is nystatin.

Nystatin is an antifungal antibiotic active against a wide range of yeasts and yeast-like fungi, including *Candida albicans*.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to the reference product cross-reference product Nystan Oral Suspension, PL 47587/0005, currently held by Vygoris Limited, which was originally granted in the UK to the Marketing Authorisation Holder E R Squibb & Sons Limited on 28/11/90 PL 00034/0130R.

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A national marketing authorisation was granted in the United Kingdom on 06 January 2023

## II. EXPERT REPORT

The applicant cross-refers to the data for Nystan Oral Suspension, PL 47587/0005 (Vygoris Limited), to which this application is claimed to be identical. This is acceptable.

## III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with that for Nystan Oral Suspension, PL 47587/0005 dated October 2021.

## PATIENT INFORMATION LEAFLET

A mock-up has been provided which has been aligned with that for Nystan Oral Suspension, PL 47587/0005, dated for 11/2021. The user test report submitted for PL 47587/0011 has been provided.

**LABEL**

Label mock-ups have been provided.

**IV. QUALITY ASPECTS****IV.1 Drug Substance****Drug substance specifications**

The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

**IV.2. Drug Product****Name**

The product has been named in line with current requirements.

**Strength, pharmaceutical form, route of administration, container and pack sizes**

Nystatin Oral Suspension is available in a 30 ml amber glass bottle, packed in a cardboard carton with a graduated, polyethylene dropper.

The appearance of the product is identical to that of the cross-reference product.

The proposed shelf life of the product is 2 years with the recommended storage condition 'Do not store above 25°C'.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

**Legal status**

Prescription only medicine (POM).

**Manufacturers**

The proposed manufacturing sites are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

**Qualitative and quantitative compositions**

The composition of the proposed product is consistent with the details registered for the cross-reference product.

**Manufacturing process & control of critical steps**

The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

**Finished product release/shelf life specifications**

The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference product.

**TSE Compliance**

None of the excipients used contain material of animal or human origin.

This product does not contain or consist of genetically modified organisms (GMO).

**V. NON-CLINICAL ASPECTS**

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new non-clinical data have been supplied and none are required.

**VI. CLINICAL ASPECTS**

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new clinical data have been supplied and none are required.

**VII. RISK MANAGEMENT PLAN (RMP)**

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

**VIII. USER CONSULTATION**

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Nystan Oral Suspension (PL 47587/0005; Vygoris Limited).

The bridging report submitted by the applicant is acceptable.

**IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION**

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

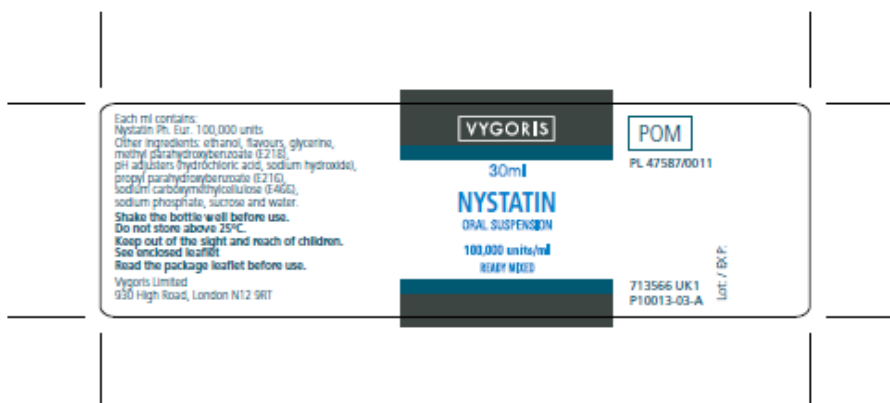
The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

Representative copies of the labels at the time of licensing are provided below.



nystatin  
oral  
suspension



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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

<b>Application type</b>	<b>Scope</b>	<b>Product information affected</b>	<b>Date of grant</b>	<b>Outcome</b>	<b>Assessment report attached Y/N</b>