LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Nystimex
(nystatin)

SE/H/1366/01/DC

This module reflects the scientific discussion for the approval of Nystimex. The procedure was finalised on 2015-01-13. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Nystimex, 100 000 IU/ml, oral suspension is a hybrid application made according to Article 10(3) of Directive 2001/83/EC. The applicant, RPH Pharmaceuticals AB, applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and DK, FI, IS, NO as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Mycostatin, 100 000 IU/ml, oral suspension authorised in SE since 1973, with Bristol-Myers Squibb AB as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Nystimex is presented in the form of an oral suspension containing 100 000 IU/ml of nystatin. The excipients are sodium carboxymethylcellulose, xylitol, peppermint oil, methyl parahydroxybenzoate and purified water. The oral suspension is filled in amber glass bottles.

II.2 Drug Substance

Nystatin has a monograph in the Ph Eur.

Nystatin is a yellow or slightly brownish powder which is practically insoluble in water. The structure of nystatin has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substance specification includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Nystimex, 100 000 IU/ml, oral suspension is formulated using excipients described in the current Ph Eur, except for peppermint oil which is controlled according to acceptable in house specifications. All raw materials used in the product are of vegetable origin/has demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The product development has taken into consideration the physico-chemical characteristics of the active substance, such as poor aqueous solubility.

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies under ICH conditions have been performed and data presented support the shelf life and storage conditions claimed in the SPC.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

For an abridged application of a locally acting, locally applied product, therapeutic equivalence with regard to efficacy and safety should be demonstrated. For Nystimex equivalence has been shown based on pharmaceutical data.

IV.1 Pharmacokinetics

Nystatin is a locally acting drug with negligible oral bioavailability. A bioequivalence study to evaluate similarity in systemic exposure is therefore not relevant.

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

The risk/benefit ratio is considered positive and Nystimex, 100 000 IU/ml, oral suspension is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Nystimex, 100 000 IU/ml, oral suspension was successfully finalised on 2015-01-13.

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Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
						Y/N (version)

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