LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Xylometazolin Apofri, 0,5 mg/ml, Nasal spray, solution (xylometazolin hydrochloride)

Asp. no: 2011-0152

This module reflects the scientific discussion for the approval of Xylometazolin Apofri 0.5 mg/ml . The procedure was finalised at 2011-10-28. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Evolan Pharma AB has applied for a marketing authorisation for Xylometazolin Apofri, 0,5 mg/ml, Nasal spray, solution. The active substance xylometazoline hydrochloride is the same as in Xylometazolin Apofri, 1 mg/ml, nässpray, lösning, marketed by Evolan Pharma AB since 2010. For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Xylometazolin Apofri is presented in the form of a nasal spray, solution, containing 0.5 mg/ml mg of xylometazoline hydrochloride. The excipients are glycerol, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium chloride and water. The solution is filled in a plastic spray bottle.

II.2 Drug Substance

The drug substance, xylometazoline hydrochloride, has a monograph in the Ph Eur. Xylometazoline hydrochloride is a white or almost white, crystalline powder which is freely soluble in water. The manufacturer of the drug substance has a valid CEP for the drug substance.

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.

II.3 Medicinal Product

Xylometazolin Apofri 0.5 mg/ml nasal spray, solution, is formulated using excipients described in the current Ph Eur. 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 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 claimed in the SPC, with no special storage precautions.

III. NON-CLINICAL ASPECTS

The pharmacodynamic, pharmacokinetic and toxicological properties of xylometazolin hydrochloride are well known. As xylometazolin is a widely used, well-known active substance, no further studies were required.

Since Xylometazolin Apofri is not considered to increase the risk to the environment beyond or above that which may be caused by other xylometazoline-containing product products, no ERA was deemed necessary.

IV. CLINICAL ASPECTS

The pharmacodynamics, clinical efficacy and safety of xylometazoline at the proposed indication are considered well known. Thus, no new clinical studies were required.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report. The applicant suggests to bridge to the user test made for Xylometazolin Apofri 1 mg/ml, nationally approved 2010-06-08. (111:2009/39654)
The bridging report submitted by the applicant has been found acceptable.

The risk/benefit ratio is considered positive and Xylometazolin Apofri 0.5 mg/ml is recommended for approval.

VI. APPROVAL

Xylometazolin Apofri 0.5 mg/ml was approved in the national procedure on 2011-10-28.

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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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