

Public Assessment Report

Oxymetazoline 0.05%w/v Nasal Spray

PL 16028/0110

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

UKPAR

TABLE OF CONTENTS

	Page
Lay Summary	3
Scientific discussion	4
Steps taken for assessment	11
Steps taken after authorisation – summary	12
Summary of Product Characteristics	13
Patient Information Leaflet	17
Labelling	19

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Galpharm Healthcare Limited a Marketing Authorisation (licence) for the medicinal product Oxymetazoline 0.05%w/v Nasal Spray (PL 16028/0110). This is a general sale list [GSL] medicine for the relief of a blocked nose in such conditions as the common cold, catarrh and hayfever.

Oxymetazoline 0.05%w/v Nasal Spray contains the active ingredient oxymetazoline, which constricts the blood vessels in the nose.

This application is a duplicate of a previously granted licence for Galpharm Nasal Decongestant Spray (PL 16028/0049).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Oxymetazoline 0.05%w/v Nasal Spray outweigh the risks, hence a Marketing Authorisation has been granted.

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

	Page
Introduction	5
Pharmaceutical assessment	6
Preclinical assessment	8
Clinical assessment	9
Overall conclusions and risk benefit assessment	10

INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Oxymetazoline 0.05%w/v Nasal Spray (PL 16028/0110) to Galpharm Healthcare Limited on 15 March 2006. The product is a general sale list [GSL] medicine.

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Galpharm Nasal Decongestant Spray (PL 16028/0049, approved on 1 January 2001).

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

The product contains the active ingredient oxymetazoline. Oxymetazoline is an alpha-adrenoceptor agonist which causes local vasoconstriction when applied to the nasal membrane.

Oxymetazoline 0.05%w/v Nasal Spray is used for the relief of nasal congestion in such conditions as the common cold, catarrh and hayfever.

PHARMACEUTICAL ASSESSMENT

PL Number: PL 16028/0110
Name of Product: Oxymetazoline 0.05%w/v Nasal Spray
Active (s): Oxymetazoline Hydrochloride
Company Name: Galpharm Healthcare Ltd.
E.C. Directive: 2001/83/EC Article 10.1(a)(i)
Legal Status: GSL

Legal basis

This is a simple abridged application for Oxymetazoline 0.05%w/v Nasal Spray. The reference product is Galpharm Nasal Decongestant Spray (PL 16028/0049) held by Galpharm Healthcare Ltd., granted 1 January 2001. The original licence was PL 00071/0175, granted 3 August 1981.

Letters of access

A letter of access is not provided. However, it is not required as the marketing authorisation holder (MAH) for the test and reference product is the same. Confirmation that the manufacturer is prepared to manufacture the product on the applicant's behalf is provided. Written confirmation that the applicant has access to all the data supporting the application is not required as the marketing authorisation holder for the test and reference product is the same.

Reference product

The SPC did not comply with the SPC NfG.
The SPC was not in line with the excipient guideline.
Part IC, Additional Data Requirements complies with *MAIL 109*.
There are no AHO substances present.

Expert reports

Satisfactory reports have been provided.

Product name

This is generic and is acceptable.

Summary of Product Characteristics (SPC)

This is in line with the reference product, but has been amended to comply with the SPC NfG.

Patient Information leaflet (PIL)

A colour mock up of the PIL has been provided. This is in line with the reference product. The PIL complies with the Guidance on Excipient in the Label and Package Leaflet of Medicinal Products for Human Use and the Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use.

Label

A colour mock up has been provided. This is in line with the reference product.

Marketing Authorisation Application (MAA) form

The sites of manufacture, assembly and batch release are in line with the reference product. The MAA form is in line with the SPC, where appropriate.

A Wholesale Dealer's Licence has been provided to support the batch release site which includes a named Responsible Person but not a named Qualified Person. This is acceptable. The formulation is in line with that of the reference product.

Appropriate annexes have been provided.

TSE

This is in line with the reference product.

Part IC: Additional Data Requirements

The manufacturing process and finished product specification are in line with the reference product.

The Drug Substance Specification is in line with the Ph.Eur.

CONCLUSION

Marketing authorisation may be granted for this product.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the cross-referenced product and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to a previously granted application for Galpharm Nasal Decongestant Spray.

No new or unexpected safety concerns arose from this application.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-referenced product. Extensive clinical experience with the active ingredient oxymetazoline is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Oxymetazoline 0.05%w/v Nasal Spray on 24 June 2005.
2	Following standard checks the MHRA informed the applicant that its application was considered valid on 28 July 2005.
3	The MHRA's assessment of the submitted data was completed on 14 September 2005.
4	Further information was requested from the company on 26 September 2005.
5	The applicant responded to further information request in a letter dated 2 December 2005.
6	The MHRA completed its assessment of the application on 28 February 2006.
7	The application was determined on 15 March 2006.

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Oxymetazoline 0.05% w/v Nasal Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The nasal solution contains Oxymetazoline (as hydrochloride) 0.05% w/v.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Oxymetazoline Nasal Spray is recommended for the relief of nasal congestion in such conditions as the common cold, catarrh and hayfever.

4.2. Posology and method of administration

Adults and Elderly

While holding upright the spray nozzle should be inserted into each nostril in turn and squeezed firmly twice while breathing in. The application may be repeated up to 2 times a day, or used at bedtime to give relief through the night.

Children

Not recommended for children under 12 years of age.

4.3. Contraindications

Hypersensitivity to any component of the medicinal product.

Patients who are receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment; patients suffering from porphyria, glaucoma, coronary artery disease, hypertension, hyperthyroidism or diabetes.

4.4. Special warnings and precautions for use

If symptoms persist, consult your doctor. Prolonged use may result in rhinitis medicamentosa and should therefore be avoided. Keep all medicines safely away from children. Do not use for more than seven days.

4.5. Interactions with other medicinal products and other forms of interaction

If you are taking other medicines, you should see your doctor for advice before taking this medicine.

4.6. Pregnancy and lactation

The safety of use in pregnancy has not been established and administration of oxymetazoline during pregnancy should be avoided.

4.7. Effects on ability to drive and use machines

None.

4.8. Undesirable effects

This medicinal product contains thiomersal (an organomercuric compound) as a preservative and therefore, it is possible that it may cause local skin reactions (e.g. contact dermatitis) and discolouration.

Benzalkonium may cause local skin reactions.

4.9. Overdose

No statement.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): S01G A04 Sympathomimetics used as decongestants

Oxymetazoline is an alpha-adrenoceptor agonist which causes local vasoconstriction when applied to nasal membrane.

5.2. Pharmacokinetic properties

When applied locally to nasal mucosa, oxymetazoline acts within a few minutes and its effects last for up to 12 hours.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride
Thiomersal
Sodium chloride
Menthol
Cineole
Camphor
Methyl salicylate
Poloxamer 188
Sodium citrate (dihydrate) (E331)
Citric acid (anhydrous) (E330)
Purified water.

6.2. Incompatibilities

None

6.3. Shelf life

2 years

6.4. Special precautions for storage

None

6.5. Nature and contents of container

White, low density polyethylene/polypropylene copolymer 15ml bottle.
White, high density polyethylene 15ml and 20ml bottle.

6.6. Instruction for use and handling (, and disposal)

None

7. MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Ltd
Hugh House
Dodworth Business Park
Dodworth
South Yorkshire
S75 3SP

8. MARKETING AUTHORISATION NUMBER

PL 16028/0110

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/03/2006

10. DATE OF REVISION OF THE TEXT

15/03/2006

Patient Information Leaflet

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

Patient Information Leaflet
Oxymetazoline 0.05% w/v Nasal Spray

Read this leaflet carefully because it contains important information for you. This medicine is available without prescription for you to treat a mild illness without a doctor's help. Nevertheless, you still need to use Oxymetazoline 0.05% w/v Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve.

In this leaflet:

1. What your medicine is and what it's used for
2. Before you take your medicine
3. How to take your medicine
4. While taking your medicine
5. Storing your medicine

1. What your medicine is and what it's used for

Oxymetazoline 0.05% w/v Nasal Spray is available in a 15ml pack. The solution contains oxymetazoline (as hydrochloride) 0.05% w/v as the active ingredient. It also contains benzalkonium chloride, thiomersal, sodium chloride, menthol, cineole, camphor, methyl salicylate, poloxamer, sodium citrate, anhydrous citric acid and purified water.

Product Licence Holder	Manufacturer
Galpharm Healthcare Ltd Upper Cliffe Road Dodworth Business Park Dodworth South Yorkshire S75 3SP	Galpharm International Ltd Upper Cliffe Road Dodworth Business Park Dodworth South Yorkshire S75 3SP

How does your medicine work?

Oxymetazoline is a decongestant, which relieves a blocked nose by constricting the blood vessels in the nose. It acts within a few minutes and lasts for hours.

What is your medicine for?

Oxymetazoline 0.05% w/v Nasal Spray can be used for the relief of nasal congestion associated with colds, catarrh and hayfever.

2. Before you take your medicine

Do not use this spray if you:

- Are allergic to any of the ingredients listed at the beginning of this leaflet.
- You suffer from porphyria (an excess of porphyrin (protein) in the blood and urine), glaucoma (an increase in pressure in the eye), coronary heart disease (arteries cannot supply enough blood to the heart), hypertension (high blood pressure), hyperthyroidism (over-active thyroid gland) or diabetes.
- You are taking Monoamine Oxidase Inhibitors (MAOIs) (medicines used to treat depression). Or within 14 days of stopping treatment.
- You are pregnant.

Taking / using other medicines

If you are taking other medicines, you should see your doctor or pharmacist for advice before taking this medicine.

3. How to take your medicine

If you do not understand these instructions or if you require any further information about your medicine, ask your doctor or pharmacist.

For nasal use only.

Adults and the elderly: Hold the container upright, place the tip of the spray nozzle in each nostril in turn and squeeze the container twice firmly as you breathe in. Repeat up to 2 times daily or use at bedtime to give relief through the night.

Children under 12 years: Not recommended.

Do not exceed the stated dose. If you may have used more spray than you should, talk to a doctor or pharmacist immediately.

This product is not suitable for long-term use. Do not use for more than seven days. If symptoms persist, consult your doctor.

4. While taking your medicine

Possible Side Effects

Prolonged use may result in rebound congestion (unusual swelling and enlargement of the nasal membranes, leading to a blocked nose following the last dose of the spray) and should therefore be avoided.

This medicinal product contains benzalkonium chloride which is an irritant and may cause skin reactions.

This product also contains thiomersal as a preservative and it is possible that this may cause local skin reactions (e.g. contact dermatitis) and discolouration. You may also experience an allergic reaction. Symptoms of such a reaction may include:

- local stinging or burning
- sneezing
- dryness of the mouth and throat

Tell your doctor if you have any known allergies.

If you notice these or any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. Storing your medicine

Do not use Oxymetazoline 0.05% w/v Nasal Spray after the expiry date shown on the bottle and carton.

This product does not require any special storage conditions.

Keep out of the reach and sight of children.

Text prepared: December 2005


Labelling

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

Carton

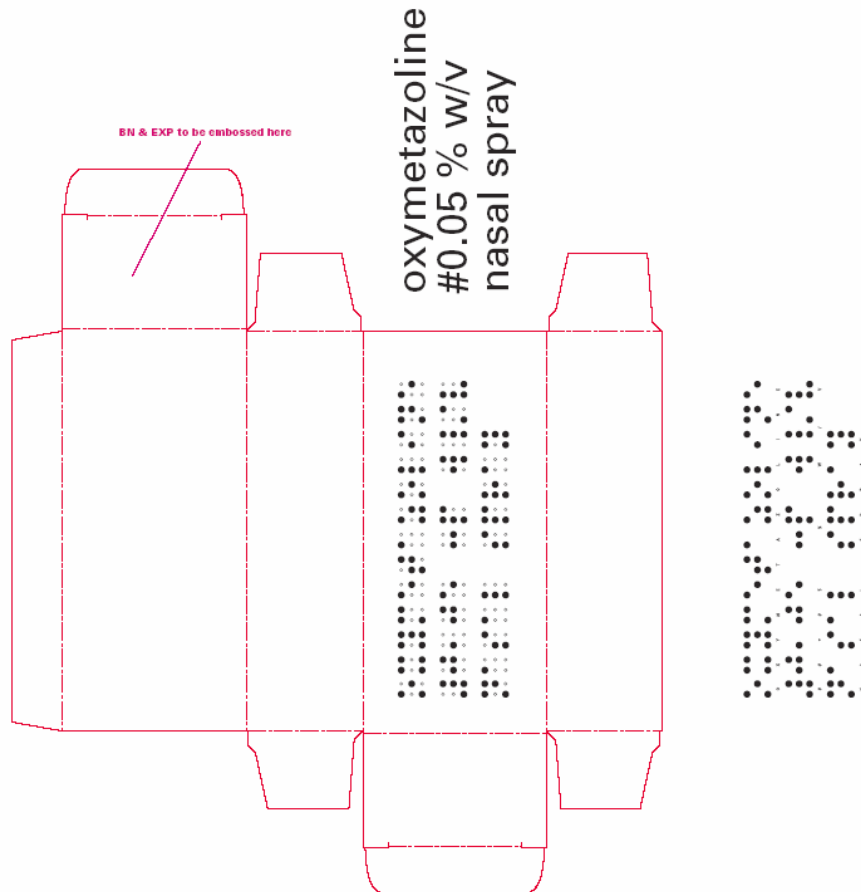



 High House - Galpharm Way - Upper Cliffe Road - Dodworth Business Park Dodworth - Barnsley - South Yorkshire - S75 3SP Tel: +44 (0) 1228 778911 - Fax: +44 (0) 1228 704852 E Mail: postmaster@galpharm.co.uk - Website: http://www.galpharm.co.uk	Artwork Name	Artwork Ref No.	Component	Version	Date	Colours Used	<input type="radio"/> None	<input type="radio"/> None
	Oxymetazoline Nasal Spray	00000	Carton	2GH	01.12.2005	<input type="radio"/> None	<input type="radio"/> None	
	Checked by	Approved by		<input type="radio"/> None	<input type="radio"/> None			
	Comments	1. Remove cutting form 2. Insert and check barcode 3. Bleeds and trapping to add if necessary		<input type="radio"/> None	<input type="radio"/> None			
	<small>© 2005 THE PROPERTY OF GALPHARM BIOPHARMACEUTICALS LTD. NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS WITHOUT THE PERMISSION OF GALPHARM - COPYRIGHT PROTECTED. ———</small> <small>CONTROLLED DOCUMENT - DO NOT COPY OR DISTRIBUTE FROM THE PERFORMANCE OF GALPHARM'S OBLIGATIONS - SUBJECT TO AGREEMENT AND CONFIDENTIALITY - WITHOUT PREVIOUS</small>					Dimensions	44mm x 28mm x 96mm	MAC 1

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

Braille



 <p>Hugh House - Galpharm Way - Upper Cliffe Road - Dodworth Business Park Dodworth - Barnsley - South Yorkshire - S75 3SP Tel: +44 (0) 1226 779911 - Fax: +44 (0) 1226 704952 E Mail: postmaster@galpharm.co.uk - Website: http://www.galpharm.co.uk</p>	Artwork Name	Artwork Ref No.	Component	Version	Date	Colours Used		
	Generic Oxymetazoline Nasal Spray	000	Braille	2 DH	31.01.2006	<input type="radio"/> None	<input type="radio"/> None	
	Checked by	Approved by					<input type="radio"/> None	<input type="radio"/> None
	Comments	1. Remove cutting form 2. Insert and check barcode 3. Bleeds and trapping to add if necessary					<input type="radio"/> None	<input type="radio"/> None
<small>SUBJECT TO THE PROPERTY OF GALPHARM INTERNATIONAL LTD - NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC OR MECHANICAL, WITHOUT THE WRITTEN PERMISSION OF GALPHARM - COPYRIGHT PROTECTED - ***** - CONTROLLED DOCUMENT - DO NOT COPY OR DISTRIBUTE - FOR THE INFORMATION OF GALPHARM'S SOLUTIONS - SUBJECT TO AGREEMENT AND CONSIDERATION - WITHOUT PREJUDICE</small>						Dimensions	MAC 1	
						44mm x 28mm x 96mm		

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

Bottle label



Artwork Name	Artwork Ref No.	Component	Version	Date	Colours Used
Oxymetazoline Nasal Spray	00000	Label	2GH	01.12.2005	<input type="radio"/> None <input type="radio"/> None <input type="radio"/> None <input type="radio"/> None <input type="radio"/> None <input type="radio"/> None
Checked by	Approved by				
Comments					
1. Remove cutting form 2. Insert and check barcodes 3. Bleeds and trapping to add if necessary					
<small>© 2005 THE PROPERTY OF GALPHARM INTERNATIONAL LTD. NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC OR MECHANICAL, WITHOUT PERMISSION IN WRITING FROM GALPHARM. COPYRIGHT PROTECTED. ———</small> <small>— CONTROLLED DOCUMENT — DO NOT COPY OR DISTRIBUTE — FOR THE INFORMATION OF GALPHARM'S SUBSIDIARIES — SUBJECT TO AGREEMENT AND CONFIDENTIALITY — VENDOR PRELIERE</small>					Dimensions 26mm x 28mm


 High House - Galpharm Way - Upper C/He Road - Donworth Business Park
 Donworth - Barnsley - South Yorkshire - S70 3SP
 Tel: +44 (0) 1226 779911 - Fax: +44 (0) 1226 704982
 E Mail: postmaster@galpharm.co.uk - Website: http://www.galpharm.co.uk

MAC 1