

Public Assessment Report

Oxymetazoline 0.05%w/v Nasal Spray

PL 16028/0100

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0100

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OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0100

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 16028/0100). 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

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Oxymetazoline 0.05%w/v Nasal Spray (PL 16028/0100) to Galpharm Healthcare Limited on 17 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 16028/0100
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

INTRODUCTION

This is an abridged application made under Article 10.1(a)(i) of Directive 2001/83/EC and is considered to be an identical product to Galpharm Nasal Decongestant Spray (PL 16028/0049). The licence for this product is also held by Galpharm Healthcare Limited and was granted on 1 January 2001.

As the applicant holds the licence for the cross-referenced product, it is taken that they have access to all data supporting the application and that they have part II data in their possession as required for regulation 10.1(a)(i) applications (*MAIL 114*, July/August 1999). A letter has been provided from the manufacturer confirming that they are prepared to manufacture the product on the applicant's behalf.

PRODUCT NAME

The name of the product is acceptable.

QUALITY / NON-CLINICAL / CLINICAL OVERALL SUMMARIES

Satisfactory summaries that the product of interest is identical to the cross-referenced licence have been provided.

MARKETING AUTHORISATION APPLICATION (MAA)

In general this MAA provides similar information to that of the cross-referenced licence (PL 16028/0049) and also includes the subsequent approved variations.

It has been confirmed that this product will not be manufactured by the alternative manufactures stated on the cross-referenced licence.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

A satisfactory SPC has been provided.

LABELLING

Colour mock-ups of the carton and bottle labels have been provided. These are acceptable.

PATIENT INFORMATION LEAFLET (PIL)

Colour mock-ups of the PIL have been provided. These are satisfactory.

PHARMACEUTICAL RECOMMENDATION

A marketing authorisation can be granted.

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.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Oxymetazoline 0.05%w/v Nasal Spray on 13 July 2004.
2	Following standard checks the MHRA informed the applicant that its application was considered valid on 26 July 2004.
3	The MHRA's assessment of the submitted data was completed on 17 December 2004.
4	Further information was requested from the company on 21 December 2004.
5	The applicant responded to further information request in a letter dated 5 April 2005.
6	Further information was requested from the company on 27 September 2005.
7	The applicant responded to further information request in a letter dated 4 November 2005.
8	The applicant was asked to respond to outstanding queries on 5 December 2005.
9	Responses to outstanding queries were supplied by the applicant in a letter dated 15 December 2005.
10	Additional information was requested from the company on 27 January 2006.
11	The applicant responded to additional information request in a letter dated 31 January 2006.
12	The MHRA completed its assessment of the application on 8 March 2006.
13	The application was determined on 17 March 2006.

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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 full list of 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. Treatment should be limited to a maximum of seven days. Keep all medicines safely away from children.

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 chloride may cause local skin irritation.

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
Levomenthol
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 Instructions for use and handling

None

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 16028/0100

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/03/2006

10 DATE OF REVISION OF THE TEXT

17/03/2006

Patient Information Leaflet

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

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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 Oxymetazoline 0.05% w/v Nasal Spray is and what it is used for
2. Before you use Oxymetazoline 0.05% w/v Nasal Spray
3. How to use Oxymetazoline 0.05% w/v Nasal Spray
4. Possible side effects
5. Storing your medicine

Oxymetazoline 0.05% w/v Nasal Spray is a solution containing oxymetazoline hydrochloride (0.05% w/v) as the active ingredient.
This solution also contains benzalkonium chloride, thiomersal, sodium chloride, levomenthol, cineole, camphor, methyl salicylate, poloxamer, sodium citrate, anhydrous citric acid and purified water.

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

1. What Oxymetazoline 0.05% w/v Nasal Spray is and what it is used for

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. Oxymetazoline 0.05% w/v Nasal Spray can be used for the relief of nasal congestion associated with colds, catarrh and hayfever.
This product is available in 15ml packs.

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2. Before you use Oxymetazoline 0.05% w/v Nasal Spray

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 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 currently taking Monoamine Oxidase Inhibitors (MAOIs) or within 14 days of stopping treatment (medicines used to treat depression).
- 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 use Oxymetazoline 0.05% w/v Nasal Spray

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. Treatment should be limited to a maximum of seven days. If symptoms persist, consult your doctor.

4. 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.

Keep all medicines out of the reach and sight of children.

Text prepared: March 2006

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Labelling

OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0100

Carton

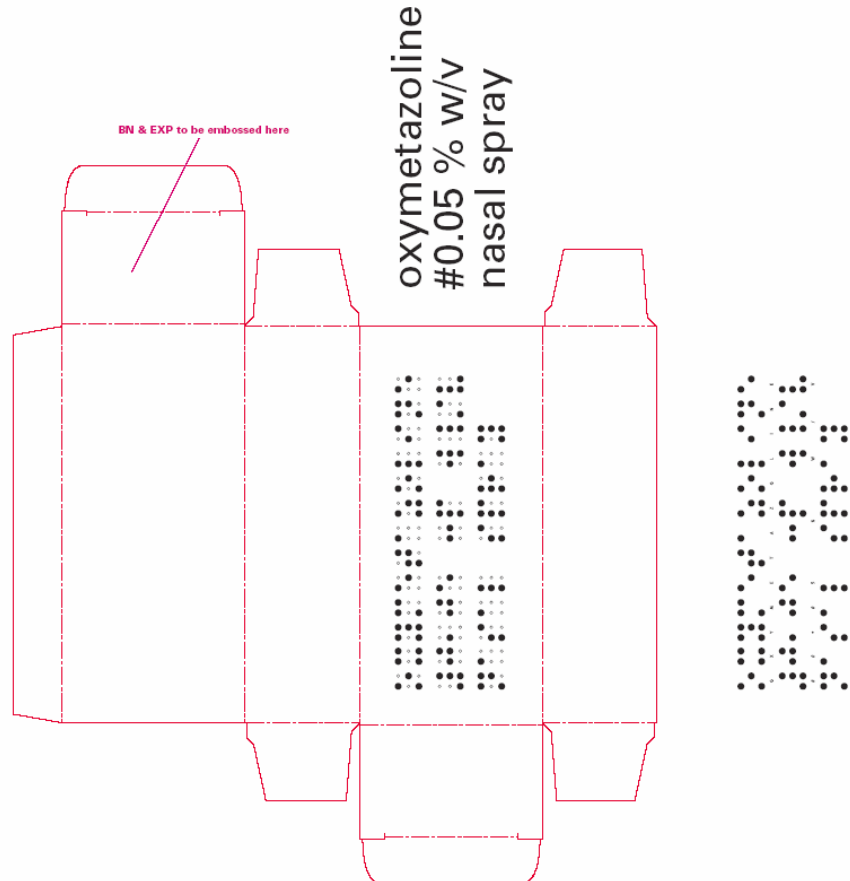



 <p>Hugh House - Galpharm Way - Upper Cliffe Road - Dodworth Business Park Dodworth - Barnsley - South Yorkshire - S75 3SP Tel: +44 (0) 1228 779911 - Fax: +44 (0) 1228 784902 E Mail: postmaster@galpharm.co.uk - Website: http://www.galpharm.co.uk</p>	Artwork Name	Artwork Ref No.	Component	Version	Date	Colours Used
	Generic Oxymetazoline Nasal Spray	000	Carton	7 DH	02.03.2006	<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
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OXYMETAZOLINE 0.05%w/v NASAL SPRAY

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	Generic Oxymetazoline Nasal Spray	000	Braille	2 DH	31.01.2006	<input type="radio"/> None <input type="radio"/> None <input type="radio"/> None	<input type="radio"/> None <input type="radio"/> None <input type="radio"/> None
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Bottle label

