Public Assessment Report

Oxymetazoline 0.05%w/v Nasal Spray

PL 16028/0110
OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

UKPAR

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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

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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.
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.
### STEPS TAKEN FOR ASSESSMENT

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

PL 16028/0110

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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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 (use, 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
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.
The medicine is available without prescription for the relief of nasal congestion due to colds, hay fever or other nasal allergies. It can be used for the relief of nasal congestion due to minor allergic rhinitis.

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

Oxymetazoline 0.05%w/v Nasal Spray is available in a 125ml pack. The solution contains oxymetazoline hydrochloride (0.05%), as the active ingredient. Oxymetazoline hydrochloride is a direct-acting vasoconstrictor that reduces nasal congestion by constricting the nasal blood vessels. The solution is supplied in a nasal spray to be used twice daily for up to 7 days. The nasal spray is for use in adults and children over 12 years of age.

2. How does your medicine work?

Oxymetazoline is a decongestant, which reduces the blood flow in the nose. It acts within about 5 minutes and lasts for hours.

3. Before you take your medicine

Do not use this spray if:

- You are allergic to any of the ingredients listed at the end of this leaflet.
- You are taking other medicines that can cause an allergic reaction such as non steroidal anti-inflammatory drugs (NSAIDs) and aspirin.
- You are taking other medicines that can cause drowsiness, such as sedatives, tranquillizers, hypnotics or other medicines which lower blood pressure such as diuretics.
- You have recently been treated with phenylephrine or pseudoephedrine.
- You have been treated with oxymetazoline for more than 7 days.
- You have taken more than one vial of oxymetazoline nasal spray in 7 days.
- You have had a head injury or have been unconscious.
- You have a history of nasal polyps or septal perforations.
- You are pregnant.

4. While taking your medicine

Possible Side Effects:

- Premature discharge of the nasal passages due to nasal congestion and enlargement of the nasal mucosa, leading to the blocking of the nasal passage.
- Tinnitus.

This medicinal product contains oxymetazoline hydrochloride, which is a vasoconstrictor and may cause side effects.

This product also contains benzalkonium chloride as a preservative. It is possible that this may cause a reaction in some people. If you experience any serious reactions, stop using the medicine and consult a doctor. You may also experience other allergic reactions. Symptoms of such a reaction may include:

- Hypersensitivity of hearing.
- Swelling of the nose and throat.

Tell your doctor if you have any known allergies.

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

5. Storing your medicine

This product contains Oxymetazoline 0.05%w/v Nasal Spray after the expiry date shown on the pack and safety issues.

This product does not require any special storage conditions.

Keep out of the reach and sight of children.

For your pharmacist

MHRA: PAR – Oxymetazoline 0.05%w/v Nasal Spray PL 16028/0110
Labelling
OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

Carton
OXYMETAZOLINE 0.05%w/v NASAL SPRAY

PL 16028/0110

Bottle label