SUDAFED 0.1% NASAL SPRAY  
(xylometazoline hydrochloride)  
PL 15513/0368  

UKPAR

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(xylometazoline hydrochloride)  
PL 15513/0368

**LAY SUMMARY**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted McNeil Products Limited a Marketing Authorisation for the medicinal product Sudafed 0.1% Nasal Spray (PL 15513/0368) on 28 March 2012. This is a General Sales List (GSL) medicine, which can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Sudafed 0.1% Nasal Spray is used, in adults and children aged 12 years and over, to help clear the stuffy, blocked-up feeling in the nose and sinuses caused by colds and allergies such as hay fever.

Sudafed 0.1% Nasal Spray contains the active ingredient xylometazoline hydrochloride, which is a topical decongestant that relieves nasal and sinus congestion.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Sudafed 0.1% Nasal Spray outweigh the risks and a Marketing Authorisation has been granted.
**SCIENTIFIC DISCUSSION**

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted McNeil Products Limited a Marketing Authorisation for the medicinal product Sudafed 0.1% Nasal Spray (PL 15513/0368) on 28 March 2012. The product is available as a General Sales List (GSL) medicine and does not require a prescription. Sudafed 0.1% Nasal Spray is indicated for the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis, and other upper respiratory tract allergies.

This is a national abridged application submitted under Article 10(1) of Directive 2001/83/EC, as amended, claiming to be a generic medicinal product of Otrivine Adult Formula Spray (Novartis Consumer Healthcare UK Limited), which was first authorised in the UK on 26 September 1988.

Xylometazoline hydrochloride, the active substance, is an imidazole α-adrenergic agonist which causes local vasoconstriction when applied topically. When a 0.1% xylometazoline hydrochloride solution is applied to the nasal mucosa the capillaries within the nasal vasculature are constricted which reduces congestion and associated symptoms of mucus hypersecretion as well as facilitating drainage of blocked secretions.

No new non-clinical or clinical data have been submitted, which is acceptable given that the application was based on being a generic medicinal product of an originator products that have been in clinical use for over 10 years.

No new or unexpected safety concerns arose during review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Sudafed 0.1% Nasal Spray outweigh the risks, and a Marketing Authorisation was granted.
PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

INN: Xylometazoline hydrochloride
Chemical Name: 2-[4-(1,1-Dimethylethyl)-2,6-dimethylbenzyl]-4,5-dihydro-1H-imidazole hydrochloride
Molecular Formula: \( \text{C}_{16}\text{H}_{24}\text{N}_{2}, \text{HCl} \)
Structure

Molecular weight: 280.8
Appearance: A white or almost white crystalline powder
Solubility: Freely soluble, in ethanol (96 per cent) and in methanol, practically insoluble in ether, chloroform and benzene

Xylometazoline hydrochloride is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance xylometazoline hydrochloride are covered by a European Directorate for the Quality of Medicines (EDQM) Certificate of Suitability.

DRUG PRODUCT

Other Ingredients

Other ingredients consist of the pharmaceutical excipients sodium hyaluronate, sorbitol, glycerol, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium chloride and water for injections.

Appropriate justification for the inclusion of each excipient has been provided.

All excipients comply with their respective European Pharmacopoeia monograph. Satisfactory Certificates of Analysis have been provided for all excipients.

None of the excipients contain materials of animal or human origin.

No genetically modified organisms (GMO) have been used in the preparation of these excipients.

Pharmaceutical Development

The objective of the development programme was to formulate a safe, efficacious, stable preservative-free sterile solution containing 0.1% (w/v) xylometazoline hydrochloride, which could be considered a generic medicinal product of Otrivine Adult Formula Spray (Novartis Consumer Healthcare UK Limited), in an innovative multi-dose/metered spray device so designed that the reservoir of product solution remains uncontaminated.

Suitable pharmaceutical development data have been provided for this application.
Comparative impurity profiles have been provided for this product and the reference product.

**Manufacturing Process**
A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at production scale and has shown satisfactory results.

**Control of Finished Product**
The finished product specification is satisfactory. Test methods have been described and adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of Analysis have been provided for any working standards used.

**Container Closure System**
The nasal spray is packaged in a white high-density polyethylene bottle, with a 3K pump system and a plastic cover. The product is packed into a cardboard carton with a Patient Information Leaflet in a pack size of one 10 ml nasal spray.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

**Stability**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product packed in the packaging proposed for marketing. Based on the results, a shelf-life of 3 years for the product in the unopened bottle has been set. A shelf-life of 6 months has been set once the bottle has been first opened. The product requires no special storage conditions.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**Bioequivalence/Bioavailability**
A bioequivalence study was not necessary to support this application for a nasal spray.

**Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labelling**
The SmPC, PIL and labelling are satisfactory from a pharmaceutical perspective.

A user consultation with target patient groups (‘user test’) on the package information leaflet has been performed on the basis of a bridging report making reference to the successful user-testing of the ‘parent’ PIL for Non-Drowsy Sudafed Dual Relief Max (PL 15513/0126, McNeil Products Limited). The text, content and layout of the proposed PIL are considered to be sufficiently similar to the approved ‘parent’ PIL. Hence, the bridging is accepted, without the need for further testing.
MAA Form (Marketing Authorisation Application)
The MAA form is pharmaceutically satisfactory.

Expert Report (Quality Overall Summary)
The quality overall summary is written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

Conclusion
The grant of Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

PHARMACODYNAMICS, PHARMACOKINETICS AND TOXICOLOGY
As the pharmacodynamic, pharmacokinetic and toxicological properties of xylometazoline hydrochloride are well-known, no further non-clinical studies are required and none have been provided.

NON-CLINICAL EXPERT REPORT (NON-CLINICAL OVERVIEW)
The applicant’s non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

ENVIRONMENTAL RISK ASSESSMENT
The Marketing Authorisation Holder has submitted an acceptable Environmental Risk Assessment, prepared in accordance with the “Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use” (EMEA/CHMP/SWP/4447/00). In the Phase I study, the exposure of the environment was evaluated. The predicted environmental concentration (PEC) in surface water was calculated as less than 0.01microgram/L, which is below the PEC action limit. Hence, the results of Phase I study, indicates that the therapeutic use of Sudafed 0.1% Nasal Spray is unlikely to pose a risk to the environment following prescribed usage.

CONCLUSION
The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY
The clinical pharmacology of xylometazoline hydrochloride is well-known.

No new clinical pharmacology data have been submitted and none are required for this type of application. A bioequivalence study was not necessary to support this application for a nasal spray. According to CPMP guidelines, bioequivalence studies are not generally required if the test product is of the same type of solution and contains the same concentration of the same active substance as the medicinal product currently approved (CPMP/QWP/EWP/1401/98 Rev.1).

EFFICACY
The efficacy of xylometazoline hydrochloride is well-known. No new efficacy data have been submitted and none are required for this type of application.

SAFETY
The safety profile of xylometazoline hydrochloride is well-known. No new safety data have been submitted with this application and none are required.

PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN
The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Suitable justification has been provided for not submitting a Risk Management Plan for this product.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC), PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
The SmPC, PIL and labelling are acceptable from a clinical perspective. The SmPC is consistent with that for the reference product. The PIL is consistent with the details in the SmPC and in-line with the current guidelines. The labelling is in-line with the current guidelines.

CLINICAL EXPERT REPORT (CLINICAL OVERVIEW)
The clinical overview is written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

CONCLUSION
The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The important quality characteristics of Sudafed 0.1% Nasal Spray are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted. As the pharmacokinetics, pharmacodynamics and toxicology of xylometazoline hydrochloride are well-known, no additional data were required.

EFFICACY
No new clinical data were submitted for this application. A bioequivalence study was not necessary to support this application for a nasal spray.

SAFETY
The safety profile of xylometazoline hydrochloride is well-known. No new safety data were submitted and none were required for this application.

PRODUCT LITERATURE
The SmPC, PIL and labelling are acceptable. The SmPC is consistent with that for the reference product. The PIL is consistent with the details in the SmPC and in-line with the current guidelines. The labelling is in-line with current guidance.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with xylometazoline hydrochloride is considered to have demonstrated the therapeutic value of the product. The benefit/risk balance is, therefore, considered to be positive.
Sudafed 0.1% Nasal Spray
(xylometazoline hydrochloride)
PL 15513/0368

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 26 February 2010.

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 11 March 2010.

3. Following assessment of the application the MHRA requested further information relating to the clinical dossier on 29 July 2010 and the quality dossier on 10 August 2010, 19 August 2010, 30 March 2011, 05 September 2011 and 20 January 2012.

4. The applicant responded to the MHRA’s requests, providing further information on the clinical dossier 21 January 2011 and the quality dossier on 24 February 2011, 28 July 2011, 22 December 2011, 03 February 2012 and 14 February 2012.

5. The application was determined and granted on 28 March 2012.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Sudafed 0.1% Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Xylometazoline Hydrochloride 1 mg /1ml of solution
For full list of excipients see 6.1.

3 PHARMACEUTICAL FORM
Nasal spray, solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
This product is indicated for the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis, and other upper respiratory tract allergies.

4.2 Posology and method of administration
Adults and children 12 years and over:
Nasal. One spray to be expressed into each nostril 2-3 times daily, as necessary.
Maximum daily dose: 3 sprays.

Use for more than seven consecutive days is not recommended, [See section 4.8].

Children under 12 years:
This product is not recommended for children under 12 years of age.

The Elderly
Experience has indicated that normal adult dosage is appropriate, [See section 5.2].

Hepatic/renal dysfunction
Normal adult dosage is appropriate, [See section 5.2].

4.3 Contraindications
This product is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

This product is contraindicated in individuals who are taking or have taken, monoamine oxidase inhibitors within the preceding two weeks.

This product is contraindicated in individuals with hypophysectomy or surgery exposing dura mater.

4.4 Special warnings and precautions for use
There is minimal systemic absorption with topically applied imidazoline sympathomimetics such as xylometazoline, however, this product should be used with caution in patients suffering coronary artery disease, hypertension, hyperthyroidism or diabetes mellitus.

4.5 Interaction with other medicinal products and other forms of interaction
Due to the low systemic absorption of xylometazoline when administered intra-nasally, interaction with drugs administered via other routes is considered unlikely.

4.6 Fertility, pregnancy and lactation
No foetal toxicity or fertility studies have been carried out in animals. In view of its potential vasoconstrictor effect, it is advisable to take the precaution of not using this product during pregnancy.

4.7 Effects on ability to drive and use machines
No special comment - unlikely to produce an effect
4.8 Undesirable effects
Xylometazoline nasal preparations are generally well tolerated following short-term use and local side effects are mild and infrequent. Localised burning, stinging, itching, soreness, dryness or irritation and sneezing may occur occasionally. Rarely, nausea and headache may occur.

Rebound congestion has been reported occasionally, particularly following longer-term use of xylometazoline.

4.9 Overdose
Symptoms and signs
Systemic action is unlikely when applied nasally due to the local vasoconstriction that inhibits absorption. If systemic absorption does occur xylometazoline as an $\alpha_2$-adrenergic agonist could be expected to produce effects similar to those of clonidine with a short lived rise in blood pressure, followed by more prolonged hypotension and sedation.

Treatment
Treatment of overdose should be supportive.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Xylometazoline is a sympathomimetic amine of the imidazoline class. It acts directly on $\alpha$-adrenoreceptors but does not act on $\beta$-receptors. When used topically as a nasal decongestant, xylometazoline acts rapidly and provides long-lasting relief. Onset of action is within minutes, the decongestant effect being prolonged and lasting for up to 10 hours.

Hyaluronic acid (as sodium hyaluronate), together with glycerol and sorbitol, acts as a humectants to moisturise the nasal mucosa.

5.2 Pharmacokinetic properties
Absorption, Distribution, Metabolism and Elimination
Little information is available concerning the absorption, distribution, metabolism and elimination of xylometazoline in man. Absorption into the nasal mucosal tissues is rapid.

Pharmacokinetics in Renal/Hepatic Impairment
There have been no specific studies of this product or xylometazoline in hepatic or renal impairment.

Pharmacokinetics in the Elderly
There have been no specific clinical studies of this product or xylometazoline in the elderly.

5.3 Preclinical safety data
Mutagenicity
There is insufficient information available to determine whether xylometazoline has mutagenic potential.

Carcinogenicity
There is insufficient information available to determine whether xylometazoline has carcinogenic potential.

Teratogenicity
There is insufficient information available to determine whether xylometazoline has teratogenic potential.

Fertility
No studies have been conducted in animals to determine whether xylometazoline has the potential to impair fertility. There is no information on the effects of this product on fertility.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Sodium hyaluronate
- Sorbitol
- Glycerol
- Disodium phosphate dihydrate
- Sodium dihydrogen phosphate dihydrate
- Sodium chloride
- Water for injection

6.2 Incompatibilities
None known

6.3 Shelf life
3 years.
This product should not be used longer than 6 months after opening.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
White HDPE bottle, with 3K pump system, plastic cover, carton box.
10ml nasal spray.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
McNeil Products Limited
Foundation Park
Roxborough Way
Maidenhead
Berkshire SL6 3UG
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)
PL 15513/0368

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
28/03/2012

10 DATE OF REVISION OF THE TEXT
28/03/2012
PATIENT INFORMATION LEAFLET

The leaflet text below is that agreed. The Marketing Authorisation Holder is required to submit the mock-up leaflet to the regulatory authorities before marketing the product.

SUDAFED 0.1% NASAL SPRAY

Xylometazoline hydrochloride

- This medicine is used to help clear the stuffy, blocked nose feeling in your nose and sinuses caused by colds and allergies such as hay fever.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
  - There are some people who should not take this medicine. To find out if you are one of them see section 2 >
  - If you have ever had a **bad reaction** to any of the ingredients. For the list of ingredients see section 6 >

- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in section 2. See section 2 >
- **Follow the dosage instructions carefully.** These are shown in the table. See section 3 >

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Sudafed 0.1% Nasal Spray is a medicine which is used to help clear the stuffy, blocked up feeling in your nose and sinuses caused by colds and allergies such as hay fever. The spray contains xylometazoline hydrochloride, which is a topical decongestant that relieves nasal and sinus congestion.

This medicine is for use in adults and children aged 12 years and over.

2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

**X Do not take this medicine...**

- If you have ever had a **bad reaction** (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you have recently had **neurosurgery**.
- If you have had your **pituitary gland** removed.
- If you are **pregnant**.

If any of these apply to you, **get advice from a doctor or pharmacist without taking Sudafed 0.1% Nasal Spray.**
UKPAR Sudafed 0.1% Nasal Spray

! Talk to your doctor or pharmacist...
- If you have high blood pressure or heart disease.
- If you have diabetes.
- If you have an overactive thyroid gland.

If any of these bullet points apply to you now or in the past, talk to a doctor or pharmacist.

! If you are pregnant or breast-feeding
- Do not take this medicine if you are pregnant.
- If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

3 How to use this medicine
Follow the instructions to ensure that you use Sudafed 0.1% Nasal Spray correctly:

- **Step 1.** Remove the plastic cap from the nozzle from Sudafed 0.1% Nasal Spray.
- **Step 2.** When using the spray for the first time, press the plunger downwards while supporting the base with your thumb as shown in the diagram and release until a single spray is delivered.
- **Step 3.** Hold the bottle upright and place the nozzle into one nostril. Press the plunger downwards and at the same time breathe in through your nose. Release the plunger and remove the nozzle from the nostril. Repeat this process for the other nostril.
- **Step 4.** Wipe the nozzle and replace the plastic cap after use.

Check the table that follows to see how much medicine to use.
- Do not use more than the stated dose shown in the table.

i Children under 12 years
This medicine is not recommended for children under 12 years.

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Adults and children aged 12 years and over</td>
<td>One spray into each nostril 2 or 3 times a day</td>
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</table>

- Do not take more than 3 doses in 24 hours.
- Do not use continuously for more than 7 days.
- If symptoms persist, talk to your doctor.

! If anyone has too much
If anyone has too much contact a doctor or your nearest Accident & Emergency Department (Casualty) taking this leaflet and pack with you.

! If you forget to take the medicine
If you forget to take a dose, take the next dose when needed provided that you do not take more than 3 doses in 24 hours. Do not take a double dose.

4 Possible side-effects
Sudafed 0.1% Nasal Spray can have side-effects, like all medicines, although these don’t affect everyone and are usually mild.
- Occasionally people may experience local irritation such as burning, soreness, dryness, stinging, itching or sneezing.
- Nausea and headache may rarely occur.
If this medicine is used continuously for long periods, congestion symptoms may return.

If you experience any side-effects not included in this leaflet or are not sure about anything, talk to your doctor or pharmacist.

5 Storing this medicine
Keep the product out of the reach and sight of children.

Do not use your medicine after the end of the month shown as an expiry date on the packaging.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6 Further information
What’s in this medicine?

The active ingredient in Sudafed 0.1% Nasal Spray is: Xylometazoline hydrochloride 1 mg in 1 ml.

Other ingredients are: Sodium hyaluronate, sorbitol, glycerol, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate sodium chloride and water for injections.

What the medicine looks like
Sudafed 0.1% Nasal Spray is a clear colourless solution in a 10 ml bottle.

Product Licence holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG.

Manufacturer: Ursapharm Arzneimittel GmbH, Industriestraße, D-66129 Saarbrücken, Germany.

This leaflet was revised May 2012.

Sudafed is a registered trade mark.

McNeil Products Ltd.
LABELLING

The labelling text below is the agreed The Marketing Authorisation Holder is required to submit the mock-up labelling to the regulatory authorities before marketing the product.

CARTON

FRONT & BACK PANELS:

SUDAFED 0.1% NASAL SPRAY

Xylometazoline hydrochloride
  • Targets nasal mucus directly
  • Works in minutes
  • Lasts up to 10 hours

SIDE PANEL 1:

SUDAFED 0.1% NASAL SPRAY

How does this product help?
Sudafed 0.1% Nasal Spray with xylometazoline hydrochloride, works in minutes to help clear stuffy noses and relieve sinus pressure caused by colds and hay fever. It also moisturises and soothes a dry nose. The metered spray gives an exact dose that lasts for up to 10 hours. Preservative free.

How to Use?

Adults and children aged 12 years and over:
1 spray into each nostril, 2 or 3 times daily.

Not recommended for children under 12 years old.

Do not use more than 3 doses in 24 hours.

Remove the plastic cap, insert nozzle into the nostril. Depress the pump by placing the fingers on either side of the nozzle. At the same time breathe in deeply through the nose. Repeat for the other nostril.

Keep out of reach and sight of children

10ml e
SIDE PANEL 2:

SUDAFED 0.1% NASAL SPRAY

Do not use if you are pregnant or breast-feeding. If you are taking any other medicine consult your doctor or pharmacist before using this product.

Continuous use for over 7 days is not recommended.
If symptoms persist discontinue use and consult your doctor.

This solution contains: Xylometazoline hydrochloride 1 mg/1 ml.

Other ingredients include: Sodium hyaluronate, sorbitol, glycerol, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium chloride, water for injections.

See leaflet for further information and full directions.

Product Licence holder:
McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

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