Medicines & Healthcare products Regulatory Agency

Public Assessment Report

Prescription Only Medicine to Pharmacy Reclassification

Sudafed Plus Blocked Nose 1mg/50mg/ml Nasal Spray Solution

xylometazoline hydrochloride 1mg/ml (0.1% w/v) and dexpanthenol 50mg/ml (5% w/v)

PL 15513/0407 - 0004

MCNEIL PRODUCTS LIMITED

TABLE OF CONTENTS

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK Government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (https://yellowcard.mhra.gov.uk/).

1 Introduction

Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution can be used for the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies in adults and children aged 12 years and over. Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution contains xylometazoline hydrochloride 1mg/ml (0.1% w/v) and dexpanthenol 50mg/ml (5% w/v).

The marketing authorisation holder[1], McNeil Products Limited, applied to change the legal status of this product from Prescription Only Medicine (POM) to a Pharmacy (P) medicine (see Background for definition).

The Medicines and Healthcare Products Regulatory Agency (MHRA) considers this product sufficiently safe to be sold as a pharmacy medicine. This report outlines the evidence that the MHRA reviewed and which led to the decision to approve the application.

2 Background

Xylometazoline hydrochloride is a topical decongestant that relieves nasal and sinus congestion, and dexpanthenol is a derivative of the vitamin pantothenic acid, which promotes healing and protects the lining of the nose.

A **Prescription Only Medicine (POM)** must be prescribed by a doctor or other authorised health professional and it must be dispensed from a pharmacy or from another specifically licensed place.

Pharmacy (P) medicines can be supplied without prescription only from pharmacies, by or under the supervision of a pharmacist.

General Sales List (GSL) medicines can be sold or supplied in retail outlets other than pharmacies by someone who is not a pharmacist.

In the UK, xylometazoline hydrochloride is already available as a single ingredient GSL nasal spray for the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies in adults and children aged 12 years and over.

There is limited experience of dexpanthenol in the UK. Current non-prescription medicines containing dexpanthenol are indicated as a supplement of multiple vitamins in situations of dietary need.

[1] A licence holder or marketing authorisation holder is the company with legal authorisation to make the medicine available to patients.

3 Proposed Terms of Reclassification

McNeil Products Limited proposed to make Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution available through pharmacies with the following terms of reclassification:

Indication: For the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies in adults and children aged 12 years and older.

Strength: xylometazoline hydrochloride 1mg/ml (0.1% w/v) and dexpanthenol 50mg/ml (5% w/v).

Formulation: nasal spray, solution.

Dose: one spray into each nostril up to 3 times a day, as necessary.

Maximum daily dose: 3 sprays in 24 hours.

Maximum pack size: 10ml bottle.

4 Prescription Only Medicine (POM) Criteria

To be reclassified from POM to P, a medicine must:

- be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- be generally used correctly (i.e. not frequently or to a wide extent used incorrectly)
- not contain substances or preparations of substances where the activity of the product or its side effects require further investigation
- not normally be prescribed by a doctor for injection (parenteral administration)

These criteria are set out in the Human Medicines Regulations 2012, regulation 62(3).

5 Assessment of suitability for Pharmacy availability

The MHRA assessed the application against the POM criteria as stated in section 4 to ascertain whether the product could be supplied without a prescription in a pharmacy setting under the supervision of a pharmacist.

5.1 POM Criteria 1

5.1.1 Direct Danger

Direct danger' means that a danger may be present if the product causes adverse reactions that cannot be managed without a doctor.

Whilst there is limited data available for this combination product containing xylometazoline hydrochloride and dexpanthenol, data was provided for xylometazoline alone, as the safety profile of this combination product is predominantly influenced by the xylometazoline component The risks associated with xylometazoline, such as rebound congestion, are already well documented, and the most recent data provided by the applicant did not demonstrate any new concerns or issues which would make this product unsuitable in a P setting.

The addition of dexpanthenol in this combination product does not affect the safety profile. There is limited data from UK use, however, the data provided by the applicant from the European countries which currently market this product as a non-prescription medicine support this.

5.1.2 Indirect Danger

“Indirect dangers” are considered to be when treatment might mask an underlying condition that requires medical attention.

There is a minimal risk of using this combination product incorrectly when supplied in a P setting. As xylometazoline nasal spray is already available as a GSL medicine, it is unlikely that there would be an increased risk of incorrect use as a P medicine where there is a greater control over the supply of the product. The addition of dexpanthenol in this combination product is unlikely to increase the risk of any indirect dangers occurring, such as the risk of delaying a diagnosis of an underlying condition, as the proposed indication is already treated in a GSL setting by xylometazoline nasal sprays.

As the indication is already well established in a GSL setting, the public are already accustomed to self-selecting xylometazoline nasal spray to control their symptoms.

The maximum approved pack size (10ml) is not likely to result in a prolonged use of the medicine, particularly as xylometazoline nasal sprays are already available as GSL medicines with a maximum pack size of 15ml. Therefore the risks associated with prolonged use, i.e. rhinitis medicamentosa, already apply to GSL medicines where there is a reduced control over their level of supply.

Furthermore, there is not considered to be an increased risk of overdose for this product as a P medicine, particularly as xylometazoline is already a GSL medicine, which is more accessible than a P medicine. No data was provided which would demonstrate an increased risk of overdose of this combination product due to the addition of dexpanthenol in this product

Therefore the first criterion has not been met.

5.2 POM Criteria 2

5.2.1 Incorrect Use

There is no evidence that Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution is frequently and to a very wide extent used incorrectly. The risk of intentional misuse related to the use of this combination product is low. There is no evidence to indicate that Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution has any abuse potential, and the increased access to this nasal spray as a P medicine is unlikely to increase this risk.

There have been very few reports of drug dependence with xylometazoline as a single ingredient. These cases have not resulted in any new safety findings. As xylometazoline is already available as a GSL medicine, the availability of this combination product as a P medicine is not expected to increase the risk of drug dependence, especially as the medicine would be available under more restrictive conditions.

Therefore the second criterion has not been met.

5.3 POM Criteria 3

5.3.1 Activity and/or adverse reactions require further investigation

Both xylometazoline hydrochloride and dexpanthenol have been available for many years and therefore there is no reason to believe that further investigation would be required in relation to their activity or side effects. Therefore, the third criterion has not been met.

5.4 POM Criteria 4

5.4.1 Is normally prescribed as an injection

This product is for nasal use only, so this criterion does not apply.

Overall, the MHRA considered that adequate evidence had been submitted to demonstrate that none of the POM criteria have been met, and therefore this product could suitably be classified as a P medicine.

6 Further details on the application

The application contained a risk management plan (RMP). RMPs are documents that contain information on a medicine's safety profile and one or more of the following:

- how any risks identified in the safety profile will be prevented or minimised in patients
- plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine
- risk factors for side effects
- measuring the effectiveness of measures taken to prevent or minimise risks.

The RMP for Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution identified the main risks associated with the product and proposed how these would be managed through the presence of the pharmacist and routine pharmacovigilance (monitoring and reporting of adverse events for a medicine, for which there are no special safety concerns) and via the product information (Summary of Product Characteristics[2], labelling and patient information leaflet[3]). No additional risk minimisation measures were proposed for the product.

7 Advice from the Commission on Human Medicines[4]

The Commission considered that the POM criteria had not been met, and therefore advised that Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution, containing xylometazoline hydrochloride 1mg/ml (0.1% w/v) and dexpanthenol 50mg/ml (5% w/v), could be approved for P availability based on the conditions outlined in section 3.

8 Conclusion

The MHRA has taken the decision to approve P legal status for Sudafed Plus Blocked Nose 1mg/50mg/ml nasal spray solution under the following conditions:

Indication: For the symptomatic relief of nasal congestion associated with the common cold,

[2] The Summary of Product Characteristics (SmPC) is a legal document describing a medicine's properties and how it can be used. SmPCs are available online via the MHRA.
[3] The label and leaflet (patient information leaflet) provide information to patients about the medicine, including information about how to use it
[4] The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. Their views are sought on reclassifications when more complex or new reclassifications of medicines are being proposed.

influenza, sinusitis, allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies in adults and children aged 12 years and older.

Strength: xylometazoline hydrochloride 1mg/ml (0.1% w/v) and dexpanthenol 50mg/ml (5% w/v).

Formulation: nasal spray, solution.

Dose: one spray into each nostril up to 3 times a day, as necessary.

Maximum daily dose: 3 sprays in 24 hours.

Maximum pack size: 10ml bottle.

Medicines and Healthcare products Regulatory Agency
August 2022