

**Public Assessment Report**

**Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray**

**(Budesonide)**

**PL 17901/0254**

**AstraZeneca UK Ltd**

## **LAY SUMMARY**

### **Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray (Budesonide)**

This is a summary of the Public Assessment Report (PAR) for Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray (PL 17901/0254). It explains how Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray.

For practical information about using Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray, patients should read the package leaflet or contact their doctor or pharmacist.

#### **What is Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray and what is it used for?**

Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray contains the active substance budesonide.

Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray is used to:

- dampen down and prevent inflammation
- treat inflammation in the nose that can occur as a result of an allergy to things such as pollen. The inflammation causes the nose to be blocked and results in sneezing, these are typical symptoms of hay fever
- reduce inflammation in the nose and help prevent these symptoms.

This medicine is identical to Rhinocort Aqua 64 micrograms Nasal Spray (PL 17901/0074), which is also held by the applicant (AstraZeneca UK Ltd) and authorised on 12<sup>th</sup> December 2003.

#### **How is Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray used?**

This medicine is for use as a nasal spray. The recommended dose is either two sprays into each nostril in the morning (if symptoms improve, this can be reduced to one spray in each nostril in the morning) or one spray into each nostril every morning and evening.

Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray is not recommended for use in children and adolescents under 18 years of age.

Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray can be obtained from a pharmacy.

For further information on how Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray is used, please see the Summary of Product Characteristics or the package leaflet available on the MHRA website.

#### **How does Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray work?**

Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray contains a substance called

budesonide which belongs to a group of medicines called corticosteroids. This medicine works as an anti-inflammatory and makes the nasal mucosa less sensitive to stimuli.

**How has Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray been studied?**

Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray is identical to the previously granted application for Rhinocort Aqua 64 micrograms Nasal Spray (PL 17901/0074; AstraZeneca UK Ltd). The company (AstraZeneca UK Ltd) has referred to their own data held for the grant of a licence for Rhinocort Aqua 64 micrograms Nasal Spray (PL 17901/0074) as the basis for the grant of a licence for Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray (PL 17901/0254).

**What are the benefits and risks of Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray?**

As Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray is considered identical to Rhinocort Aqua 64 micrograms Nasal Spray (PL 17901/0074), its benefits and risks are taken as being the same as those for Rhinocort Aqua 64 micrograms Nasal Spray (PL 17901/0074).

**Why is Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray approved?**

No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray outweigh the identified risks; and the grant of a Marketing Authorisation was recommended.

**What measures are being taken to ensure the safe and effective use of Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray?**

A satisfactory pharmacovigilance system has been provided to monitor the safety of this product.

**Other information about Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray**

A Marketing Authorisation was granted in the UK on 15<sup>th</sup> January 2009.

For more information about using Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray, read the package leaflet, or contact your doctor or pharmacist.

The full PAR for Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray follows this summary.

This summary was last updated in January 2015.

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**Please note that the legal status for this product has been changed from prescription only medicine (POM) to pharmacy (P). This also resulted in a change in the pack size.**

## **I Introduction**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Market Authorisation to AstraZeneca UK Ltd for the medicinal product Rhinocort<sup>®</sup> 64 micrograms Nasal Spray on 15<sup>th</sup> January 2009. This prescription only medicine (POM) is used in the treatment of seasonal and perennial allergic rhinitis and vasomotor rhinitis. In addition, the treatment of nasal polyps has also been included. These proposed indications are in accordance with the registered indications for the reference product.

Following a variation application the legal supply status has been changed from prescription only medicine (POM) to pharmacy (P), which has also resulted in a change in the pack size to 120 actuations only.

This is a national abridged simple application for a nasal spray containing 64 micrograms of micronised budesonide per actuation. The application has been submitted in accordance with Article 10c of Directive 2001/83/EC, as amended. The reference product, Rhinocort<sup>®</sup> Aqua 64 micrograms Nasal Spray (PL 17901/0074), was licensed for use in the UK in December 2003 (MAH: AstraZeneca UK Limited).

The Market Authorisation Holder for the drug product and the reference product are the same. A letter of informed consent granting permission to cross-refer to the reference product dossier is not therefore necessary.

## II Quality aspects

The proposed product contains micronised budesonide as the active substance. Further information e.g. in the form of a Certificate of Suitability, has not been provided for the drug substance. Instead, the applicant has provided a signed Quality Expert Statement which confirms that the drug substance material is identical to the drug substance material used in the manufacture of the reference product with respect to controls, packaging and specifications.

The applicant has provided a copy of the drug substance specification for budesonide micronised material. Taking into account the applicant's signed Quality Expert statement that has been provided, further provision of information in this area is considered unnecessary.

The proposed product is comprised of a suspension containing budesonide micronised packaged in a bottle with spray pump and nasal applicator. Each actuation contains 64 micrograms of budesonide (1.28 mg/ml). The composition details for the proposed product are identical to those for the reference product.

A narrative description of the manufacturing process has been made available which is in accordance with that stated for the reference product. A copy of a flow chart of the manufacturing process has also been included and details of the in-process controls have been made available. A copy of the manufacturing authorisation for the relevant site has been provided.

A copy of the proposed finished product specification has been provided. All parameters and acceptance criteria that are stated on this document are in accordance with the current registered finished product specification for PL 17901/0074.

The product is contained in a glass amber bottle with a polypropylene spray pump and nasal applicator containing 120 actuations.

The product has a 2-year shelf-life with the following conditions: the product should be used within 2 months of starting treatment. Additional storage conditions are 'Do not store above 30°C and Do not refrigerate or freeze'.

The quality data for this application are consistent with those previously assessed for the Marketing Authorisation for Rhinocort® Aqua 64 micrograms Nasal Spray (PL 17901/0074) and, as such, have been judged to be satisfactory. The grant of a Marketing Authorisation is recommended.

### **III Non-clinical aspects**

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data has been supplied and none are required.

The grant of a Marketing Authorisation is recommended.

### **IV Clinical aspects**

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The grant of a Marketing Authorisation is recommended.

### **Pharmacovigilance System**

A satisfactory pharmacovigilance system has been provided to monitor the safety of this product.

### **V User consultation**

A user consultation with target patient groups on the PIL has been performed on the basis of a bridging report making reference to the leaflet for Rhinocort Aqua 64 micrograms Nasal Spray (PL 17901/0074). The bridging report submitted by the applicant is acceptable.

### **VI Overall conclusion, benefit/risk assessment and recommendation**

The quality of the product is acceptable, and no new non-clinical or clinical concerns have been identified. The applicant's product is identical to the reference product. The benefit-risk assessment is, therefore, considered to be positive.

## Annex 1 - Table of content of the PAR update

### Steps taken after the initial procedure with an influence on the Public Assessment Report

The following table lists some non-safety updates to the Marketing Authorisation for this product that has been approved by the MHRA since the product was first licensed. The table includes updates that are detailed in the annex to this PAR. This is not a complete list of the post-authorisation changes that have been made to this Marketing Authorisation.

<b>Date submitted</b>	<b>Application type</b>	<b>Scope</b>	<b>Outcome</b>
22/01/2009	Type II	To change the legal classification status from POM to P with consequential changes to SmPC sections 1, 4.1, 4.2, 4.4, 4.5, 4.7, 5.2, 6.4, 6.5 and 6.6, the labelling and the patient information leaflet.	Variation granted 24/04/2009
11/11/2014	Type IB	To update the patient information leaflet (PIL) in line with the latest QRD template, and to add the adverse event reporting statement. Consequentially, sections 2, 4, 5.1 and 6 of the SmPC have been updated.	Variation granted 18/12/2014



**Reference:** PL 17901/0254 - application 0037

**Product:** Rhinocort<sup>®</sup> Hay Fever 64 micrograms, Nasal Spray

**MAH:** AstraZeneca UK Ltd

**Active Ingredient:** Budesonide

**Reason:**

To update the patient information leaflet (PIL) in line with the latest QRD template and to add the adverse event reporting statement. Consequentially, sections 2, 4, 5.1 and 6 of the SmPC have been updated.

**Supporting evidence**

The applicant has submitted updated sections of the SmPC and the leaflet.

**Evaluation**

The amended sections of the SmPC and the leaflet mock-up are satisfactory.

**Conclusion**

The variation was approved on 18<sup>th</sup> December 2014 and the updated SmPC fragments and the PIL have been incorporated into this Marketing Authorisation. The proposed changes are acceptable.

**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) Updated**

Following approval of the variation on 18<sup>th</sup> December 2014 the SmPC was updated. In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.

### **PATIENT INFORMATION LEAFLET (PIL) Updated**


Following approval of the variation on 18<sup>th</sup> December 2014 the PIL was updated. In accordance with Directive 2010/84/EU the Patient Information Leaflet (PIL) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.


LABELLING

**RHINOCORT® HAY FEVER**  
**64 micrograms Nasal Spray**  
**Budesonide 120 Sprays**  
 Each spray contains 64 micrograms of budesonide. For nasal inhalation.  
 The Marketing Authorisation Holder for Rhinocort Hay Fever is AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.

Keep out of reach and sight of children. Do not store above 30°C. Do not refrigerate or freeze. Keep the bottle in an upright position. Do not use if you are under 18 years of age. Do not use more than two sprays in each nostril in a day. Use within two months of opening. Please read the enclosed leaflet. Shake before use. **Important:** Pump may need to be primed before use (see enclosed instructions).

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 PL 17901/0254  
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**RHINOCORT® HAY FEVER**  
**64 micrograms Nasal Spray**  
**Budesonide 120 Sprays**

For nasal inhalation. Keep out of reach and sight of children. Do not store above 30°C. Do not refrigerate or freeze. Keep the bottle in an upright position. Use within two months of opening. Before use, please read the enclosed leaflet. Shake before use. **Important:** Pump may need to be primed before use (see enclosed instructions). **Directions:** Adults including Elderly: two sprays into each nostril regularly each morning, may be reduced to one spray into each nostril if symptoms controlled. Do not use more than two sprays in each nostril in a day. If symptoms persist for longer than two weeks consult your doctor or pharmacist. Do not use continuously for more than three months without consulting your doctor. Do not use in Children and Adolescents under 18 years.

**RHINOCORT® HAY FEVER**  
**64 micrograms Nasal Spray**  
**Budesonide 120 Sprays**

Each spray contains 64 micrograms of budesonide. Also contains disodium edetate, microcrystalline cellulose (E460), carboxymethyl-cellulose sodium (E466), glucose anhydrous, hydrochloric acid, polysorbate 80 (E433), purified water and the preservative potassium sorbate (E202). The Marketing Authorisation Holder for Rhinocort Hay Fever is AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK. Rhinocort is a Trade Mark of the AstraZeneca group of companies. © AstraZeneca 2009 PL 17901/0254 MA 010/00202

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