Beclometasone Dipropionate 50 micrograms per spray  
Aqueous Nasal Spray

PL 16431/0178

UKPAR

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BECLOMETASONE DIPROPIONATE 50 MICROGRAMS PER SPRAY AQUEOUS NASAL SPRAY

PL 16431/0178

LAY SUMMARY

This is a summary of the public assessment report (PAR) for Beclometasone Dipropionate 50 micrograms per spray Aqueous Nasal Spray (PL 16431/0178). This medicinal product will be referred to as Beclometasone Dipropionate Nasal Spray in the remainder of this summary.

This summary explains how Beclometasone Dipropionate 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 Beclometasone Dipropionate Nasal Spray.

For practical information about using Beclometasone Dipropionate Nasal Spray, patients should read the package leaflet or contact their doctor or pharmacist.

What is Beclometasone Dipropionate Nasal Spray and what is it used for?
This medicine is the same as the ‘reference product’ Beclometasone Dipropionate 50 micrograms / dose Nasal Spray. The company that owns the reference product submitted an application for Beclometasone Dipropionate Nasal Spray, using the reference product as a basis for the grant of an identical Marketing Authorisation (informed consent).

Beclometasone Dipropionate Nasal Spray is used for the treatment and prevention of allergic rhinitis, including hayfever.

How does Beclometasone Dipropionate Nasal Spray work?
Beclometasone dipropionate is a man-made corticosteroid (or steroid). Corticosteroids are hormones that are made naturally by the adrenal glands and have many important functions. One of these functions is to control inflammatory responses in the body; in the case of Beclometasone Dipropionate Nasal Spray the active ingredient is administered in the nose to prevent inflammation there, which may be the cause of sneezing, or an itchy, blocked or runny nose.

How is Beclometasone Dipropionate Nasal Spray used?
The bottle should be shaken before use and, with one nostril closed off and their head bent forward slightly, the patient should carefully insert the applicator into the other nostril and press down firmly on the white collar to produce a fine spray inside the nose. A second spray should be squirted into the same nostril and then the same process repeated for the second nostril. Full instructions about using this medicine are available in the package leaflet.

The usual dose taken is two sprays into each nostril twice a day. The maximum daily dose is a total of eight sprays. Once symptoms have improved, patients may be able to reduce the dose to one spray into each nostril twice a day. However, if symptoms become worse they should increase treatment to the usual dose.
Beclometasone Dipropionate Nasal Spray can be obtained from pharmacies without a prescription.

**What benefits of Beclometasone Dipropionate Nasal Spray have been shown in studies?**
Beclometasone Dipropionate Nasal Spray is considered to be identical to the previously authorised medicine Beclometasone Dipropionate 50 micrograms / dose Nasal Spray, with the same benefits and risks. So no new studies have been provided for Beclometasone Dipropionate Nasal Spray but reference is made to the Marketing Authorisation for Beclometasone Dipropionate 50 micrograms / dose Nasal Spray.

**What are the possible side effects from Beclometasone Dipropionate Nasal Spray?**
Patients very rarely suffer side effects when taking Beclometasone Dipropionate Nasal Spray. For the full list of all side effects reported with Beclometasone Dipropionate Nasal Spray, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

**Why is Beclometasone Dipropionate Nasal Spray approved?**
The MHRA decided that the benefits of Beclometasone Dipropionate Nasal Spray are greater than its risks and recommended that it be approved for use.

**What measures are being taken to ensure the safe and effective use of Beclometasone Dipropionate Nasal Spray?**
Relevant safety information has been included in the Summary of Product Characteristics and the package leaflet for Beclometasone Dipropionate Nasal Spray, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

**Other information about Beclometasone Dipropionate Nasal Spray**
Marketing Authorisations were granted in the UK on 26 August 2014.

For more information about Beclometasone Dipropionate Nasal Spray, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in October 2014.

The full PAR for Beclometasone Dipropionate Nasal Spray follows this summary.
SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Ayrton Saunders Ltd a Marketing Authorisation for the medicinal product Beclometasone Dipropionate 50 micrograms per spray Aqueous Nasal Spray (PL 16431/0178) on 26 August 2014. This medicinal product is a pharmacy-only medicine (P).

Beclometasone Dipropionate 50 micrograms per spray Aqueous Nasal Spray is indicated for the treatment and prevention of allergic rhinitis including hayfever in adults aged 18 years and over. The drug has a potent anti-inflammatory effect within the respiratory tract.

This application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to the Marketing Authorisation for Beclometasone Dipropionate 50 micrograms / dose Nasal Spray (PL 16431/0121). This reference product was first authorised to Parkfields Pharmaceuticals Limited on 27 August 1997 (under Marketing Authorisation number: PL 14229/0030). On 11 June 2001 ownership of the product was transferred to Miza Pharmaceuticals (UK) Limited (under Marketing Authorisation number: PL 18856/0014). On 1 July 2003 ownership of the product was transferred to Inyx Pharma Limited (under Marketing Authorisation number: PL 20165/0001). On 28 February 2008 ownership of the product was transferred to Ayrton Saunders Limited (under Marketing Authorisation number: PL 16431/0121), the current Marketing Authorisation Holder for the reference product.

Beclometasone dipropionate is a glucocorticoid. It is a synthetic corticosteroid esterified at the 17 position and is more potent topically than systemically. This drug is currently only used topically for its anti-inflammatory activity. In addition to the local anti-inflammatory action it exerts, it also has immunosuppressive activity. There are a number of factors contributing to the mechanisms behind these actions. First and foremost, the drug inhibits the adherence of neutrophils and monocyte-macrophages to the capillary endothelial cells of the inflamed area. Secondly it obstructs the effect of macrophage migration inhibitory factor. Finally, beclometasone dipropionate also decreases the activation of plasminogen to plasmin and, by inhibition of phospholipase A2 activity, it reduces the formation of prostaglandins and leukotrienes in the local tissue.

No new data were submitted nor were necessary for this simple application, as the data are identical to those of the previously granted product.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 16431/0178
PROPRIETARY NAME: Beclometasone Dipropionate 50 micrograms per spray Aqueous Nasal Spray
ACTIVE: Beclometasone dipropionate
COMPANY NAME: Ayrton Saunders Ltd
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: P

1. INTRODUCTION
This is an abridged application for Beclometasone Dipropionate 50 micrograms per spray Aqueous Nasal Spray, submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Beclometasone Dipropionate 50 micrograms / dose Nasal Spray (PL 16431/0121). The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name
The name of the product is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The nasal spray is of the same strength and form and has the same route of administration as the reference product.

Beclometasone Dipropionate Aqueous Nasal Spray is supplied in a white plastic (high density polyethylene) bottle fitted with a screw on pump covered by a dustcap. The bottle provides 200 sprays.

2.3 Legal status
The medicinal product is available from pharmacies without a prescription.

2.4 Marketing Authorisation Holder
Ayrton Saunders Ltd, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire WA7 1NU, United Kingdom

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers
The manufacturing sites are identical to those of the reference product and are acceptable.

2.6 Qualitative and quantitative composition
The product’s composition is identical to that of the reference product and is acceptable.

2.7 Manufacturing process
The manufacturing process is identical to that of the reference product and is acceptable.
2.8 Finished product/shelf-life specification
The finished product specification is identical to that of the reference product and is acceptable.

2.9 Drug substance specification
The drug substance specification is identical to that of the reference product and is acceptable.

2.10 TSE Compliance
None of the excipients contain materials of animal or human origin.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application because the product is identical to a product that is already authorised.

3. EXPERT REPORTS
These are acceptable.

4. PRODUCT NAME AND APPEARANCE
The name of the product and its appearance are essentially identical to those of the reference product and are acceptable.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The Summary of Product Characteristics is identical to that of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and is acceptable.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
The PIL and labels are identical to those of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and are acceptable.

7. CONCLUSION
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

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

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA).

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

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 Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

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

QUALITY
The data for this application are consistent with those previously assessed for the Marketing Authorisation for Beclometasone Dipropionate 50 micrograms / dose Nasal Spray (PL 16431/0121) and, as such, has been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for this type of application.

EFFICACY
The product is identical to that previously licensed; therefore, no efficacy data are needed.

SAFETY
No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE
The SmPC, PIL and labels are identical to those previously approved, apart from the necessary administrative updates to reflect the change in Marketing Authorisation.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the reference product. The benefit/risk balance is therefore considered to be positive.
STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 8 April 2009.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 20 April 2009.
5. The application was granted on 26 August 2014.
STEPS TAKEN AFTER INITIAL PROCEDURE – SUMMARY

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

Label:

Please read the enclosed leaflet before use.
Not for use by children or adolescents under 18 years of age.
Do not use more than eight sprays in a day. Shake gently before use.
The active substance is beclomethasone dipropionate 50 micrograms per spray.
Also contains benzalkonium chloride, phenylethanol, dextrose, polysorbate 80, dispersible cellulose and purified water.

Marketing Authorisation Holder:
Ayrton Saunders Ltd.,
9 Arkwright Road, Astmoor
Industrial Estate, Runcorn,
Cheshire, WA7 1WU

Contains 200 metered sprays.

Keep out of the sight and reach of children.

Store below 25°C.
Do not refrigerate.
Protect from light.

Discard three months after first use.

Lot: PL 16431/0179

Exp:
Carton:

For further information refer to the enclosed leaflet.

The active substance is beclometasone dipropionate 50 micrograms per spray.

Also contains benzalkonium chloride phenylethanol, dextrose, polysorbate 80, dispersible cellulose, and purified water.

Store below 25°C. Do not refrigerate. Protect from light.

Discard three months after first use.

Keep out of the sight and reach of children.

PL 16431/0178
Marketing Authorisation Holder:
Aytton Saunders Ltd, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU

Dose:

Adults over 18 years of age:

Shake gently before use.

Two sprays into each nostril twice daily.

The product is not recommended for children or adolescents under 18 years of age.

Do not exceed 8 sprays in 24 hours.

If symptoms have not improved within 14 days, consult your doctor or pharmacist.

Do not use this product continuously for more than 3 months without consulting your doctor or pharmacist.

The use of Beclometasone Dipropionate should be avoided during pregnancy unless thought essential by the doctor.

Beclometasone Dipropionate 50 micrograms per spray
Aqueous Nasal Spray
For nasal use only
200 metered sprays
For the treatment of allergic rhinitis, including hayfever.

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