Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nasacort Allergy 55 micrograms/dose nasal spray, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Triamcinolone acetonide

Bottles of NASACORT Allergy contain either 6.5 g or 16.5 g of suspension (with 3.575 mg or 9.075 mg triamcinolone acetonide respectively). One delivered dose contains 55 micrograms of triamcinolone acetonide.

Excipient with known effect: 15 micrograms of benzalkonium chloride/delivered dose.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray,suspension.

It is anunscented, off-white thixotropic suspension of microcrystalline triamcinoloneacetonide in an aqueous medium.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

NASACORT Allergy is indicated for the treatment of symptoms of seasonal allergic rhinitis.

4.2 Posology and method of administration

Posology
Patients aged 18 years and over: The recommended starting dose is 220 micrograms as 2 sprays in each nostril once daily. Once symptoms are controlled patients can be maintained on 110 micrograms (1 spray in each nostril once daily).

Without medical supervision, Nasacort Allergy is not recommended for use longer than three months. If symptoms of seasonal allergic rhinitis are not relieved or if they worsen within 14 days, a physician must be consulted.

Special population
Paediatric population
NASACORT Allergy is not recommended in children and adolescents under 18 years of age.

Method of administration
NASACORT Allergyis for nasal use only.
It is important to shake the bottle gently before each use.

Each actuation delivers 55 micrograms of triamcinolone acetonide from the nose piece to the patient (estimated from in vitro testing) after an initial priming of 5 sprays until a fine mist is achieved. NASACORT Allergy will remain adequately primed for 2 weeks. If the product is unused for more than 2 weeks, then it can be adequately reprimed with one spray. The nozzle should be pointeda way from you while you are doing this.

After using the spray: Wipe the nozzle carefully with a clean tissue or handkerchief, and replace the cap.

If the spray does not work and it may be blocked, clean it as follows. NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

The nasal spray should be cleaned at least once a week or more often if it gets blocked.

TO CLEAN THE SPRAY

1. Remove the cap and the spray nozzle only* (pull off).

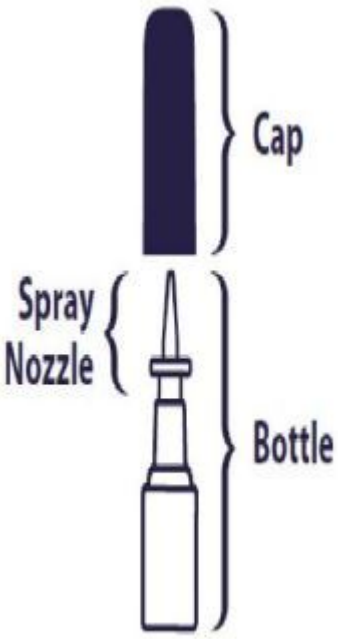
2. Soak the cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.

3. Shake or tap off the excess water and allow to air-dry.

4. Re-fit the spray nozzle.

5. Prime the unit as necessary until a fine mist is produced and use as normal.

* Part as indicated on diagram below,



Also, the bottle should be discarded after 30 actuations or within one month of starting treatment (6.5 g pack), or after 120 actuations or within 2 months of starting treatment (16.5 g pack). Do not transfer any remaining suspension to another bottle.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If there is any reason to suppose that adrenal function is impaired, care must be taken while transferring patients from systemic steroid treatment to NASACORT Allergy.

In clinical studies with NASACORT Allergy administered intranasally, the development of localised infections of the nose and pharynx with *Candida albicans* has rarely occurred. When such an infection develops it may require treatment with appropriate local therapy and temporary discontinuation of treatment with NASACORT Allergy.

Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, NASACORT Allergy should be used with caution until healing has occurred.

Systemic effects of nasal corticosteroids may occur, particularly when used for prolonged duration or at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations (may vary as per the potency, dosage form and pharmacokinetic properties (lipophilicity, volume of distribution and elimination half-life) of the steroid). Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence of using higher than recommended doses, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

The risks associated with sudden discontinuation of corticosteroids after prolonged use may include exacerbation or recurrence of the underlying disease, adrenocortical insufficiency or steroid withdrawal syndrome. However, these effects are extremely rare for nasal corticosteroids, and much less likely to occur with nasal corticosteroids than with oral corticosteroids.

Glaucoma and/or cataracts have been reported in patients receiving nasal corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma and/or cataracts.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

NASACORT Allergy contains benzalkonium chloride, long term use may cause oedema of the nasal mucosa.

Paediatric population
NASACORT Allergy is not recommended in children and adolescents under 18 years of age.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.
Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

Clinical experience in pregnant women is limited. In animal studies, corticosteroids have been shown to induce teratogenic effects. Triamcinolone acetonide may pass into human breast milk. Triamcinolone acetonide should not be administered during pregnancy or lactation unless the therapeutic benefit to the mother is considered to outweigh the potential risk to the foetus/baby.

4.7 Effects on ability to drive and use machines

Nasacort Allergyhas no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse reactions reported in clinical trials with NASACORT Allergy most commonly involved the mucous membranes of the nose and throat.

The following terminologies have been used in order to classify the occurrence of adverse reactions:
Very common (≥ 1/10); Common (≥ 1/100 to <1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to < 1/1,000); Very rare (1/10,000); and not known (cannot be estimated from the available data).

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

The most frequent adverse reactions were:

- Infections and infestations

Common: flu syndrome, pharyngitis, rhinitis

- Immune system disorders

Not known: hypersensitivity (including rash, urticaria, pruritus and facial oedema)

- Endocrine disorders

Not known: steroid withdrawal syndrome (see section 4.4)

- Psychiatric disorders

Not known: insomnia

- Nervous system disorders

Common: headache

Not known: dizziness, alterations of taste and smell

- Eye disorders

Not known: chorioretinopathy, cataract, glaucoma, increased ocular pressure, blurred vision (see section 4.4)

- Respiratory, thoracic and mediastinal disorders

Common: bronchitis, epistaxis, cough

Rare: nasal septum perforations

Not known: nasal irritation, dry mucous membrane, nasal congestion, sneezing, dyspnoea

- Gastrointestinal disorders

Common: dyspepsia, tooth disorder

Not known: nausea

- General disorders and administration site conditions

Not known: fatigue

- Investigations

Not known:decreased blood cortisol

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

Like any other nasally administered corticosteroid, acute overdosing with Nasacort Allergyis unlikely in view of the total amount of active ingredient present. In the event that the entire contents of the bottle were administered all at once, via either oral or nasal application, clinically significant systemic adverse events would most likely not result. The patient may experience some gastrointestinal upset if taken orally.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, Corticosteroids, ATC code: R 01 AD11.

Mechanism of action
Triamcinolone acetonide is a more potent derivative of triamcinolone and is approximately 8 times more potent than prednisone. Although the precise mechanism of corticosteroid antiallergic action is unknown, corticosteroids are very effective in the treatment of allergic diseases in man.

Pharmacodynamic effects
NASACORT Allergy does not have an immediate effect on allergic signs and symptoms. An improvement in some patient symptoms may be seen within the first day of treatment with NASACORT Allergy and relief may be expected in 3 to 4 days. When NASACORT Allergy is prematurely discontinued symptoms may not recur for several days.

In clinical studies performed in adults and children at doses up to 440 microgram/day intranasally, no suppression of the Hypothalamic-Pituitary-Adrenal (HPA) axis has been observed.

5.2 Pharmacokinetic properties

Single dose intranasal administration of 220 micrograms of Nasacort Allergyin normal adult subjects and in adult patients with allergic rhinitis demonstrated low absorption of triamcinolone acetonide. The mean peak plasma concentration was approximately 0.5 ng/ml (range 0.1 to 1 ng/ml) and occurred at 1.5 hours post dose. The mean plasma drug concentration was less than 0.06 ng/ml at 12 hours and below the assay detection limit at 24 hours. The average terminal half life was 3.1 hours. Dose proportionality was demonstrated in normal subjects and in patients following a single intranasal dose of 110 micrograms or 220 micrograms Nasacort Allergy. Following multiple doses in paediatric patients, plasma drug concentrations, AUC, C_{max} and T_{max} were similar to those values observed in adult patients.

5.3 Preclinical safety data

In pre-clinical studies, only effects typical of glucocorticoids were observed.

Like other corticosteroids, triamcinolone acetonide (administered by inhalation or other routes) has been shown to be teratogenic in rats and rabbits, resulting in cleft palate and/or internal hydrocephaly and axial skeletal defects. Teratogenic effects, including CNS and cranial malformations, have also been observed in non-human primates.

No evidence of mutagenicity was detected in *in vitro* gene mutation tests.

Carcinogenicity assays in rodents show no increase in the incidence of individual tumour types.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

microcrystalline cellulose and carmellose sodium (dispersible cellulose)
polysorbate 80
purified water
anhydrous glucose
benzalkonium chloride (50% w/v solution)
disodium edetate
hydrochloric acid or sodium hydroxide (for pH-adjustment).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 2 years.

After first opening: 1 month for the 6.5 g (30 actuation) pack and 2 months for the 16.5 g (120 actuations) pack

6.4 Special precautions for storage

Do not store above 25°C

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

NASACORT Allergyis contained in a 20 ml high density polyethylene (HDPE) bottle fittedwith a metered-dose spray pump unit with a polypropylene cap.

One bottle ofNASACORT Allergy contains either 6.5 gor 16.5 g of suspension, providing 30 or 120 actuations respectively.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine
France

8 MARKETING AUTHORISATION NUMBER

PA23180/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th December 2011
Date of last renewal: 20th July 2016

10 DATE OF REVISION OF THE TEXT

August 2023