

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

NASACORT 55 micrograms/dose, nasal spray, suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Bottles of NASACORT 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 an unscented, off-white, thixotropic suspension of microcrystalline triamcinolone acetonide in an aqueous medium.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Posology

Patients aged 12 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).

Paediatric patients aged 6 to 12 years: The recommended dose is 110 micrograms as 1 spray in each nostril once daily. In patients with more severe symptoms, a dose of 220 micrograms may be used. But once symptoms are controlled, patients should be maintained on the lowest effective dose (see section 4.4 and 5.1).

Special population

Paediatric population

Until further evidence is available, continuous use beyond 3 months in children under 12 years is not recommended.

Method of administration

NASACORT is for nasal use only.

It is important to shake the bottle gently before each use.

Each actuation delivers 55 micrograms 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 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 pointed away 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.

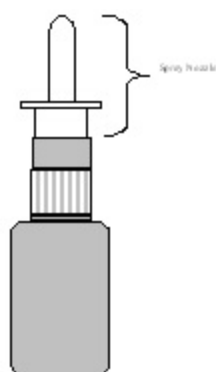
If the spray does not work and it may be blocked, clean it as follows. NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

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.

In clinical studies with NASACORT 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.

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

Systemic effects of nasal corticosteroids may occur, particularly 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. 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.

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 contains benzalkonium chloride, an irritant, which may cause skin reactions.

Paediatric population

As experience with NASACORT in children under 6 years of age is limited, use in this age group is not recommended.

Reduction in growth velocity has been reported in children receiving nasal corticosteroids, including NASACORT at licensed doses. See section 5.1.

It is recommended that the height of children receiving treatment with nasal corticosteroids is regularly monitored. Therapy should be managed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist. The long-term effects of reduction in growth velocity associated with nasal corticosteroids, including the impact on final adult height are unknown.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction with other medicaments are known.

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

4.8 Undesirable effects

The adverse events reported in clinical trials with NASACORT 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 $\geq 1/10$; Common $\geq 1/100$ and $< 1/10$; Uncommon $\geq 1/1,000$ and $< 1/100$; Rare $\geq 1/10,000$ and $< 1/1,000$; 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 in adults and children 6 years of age and older were:

- Infections and infestations

Common: flu syndrome, pharyngitis, rhinitis

- Immune system disorders

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

- Psychiatric disorders

Not known: insomnia

- Nervous system disorders

Common: headache

Not known: dizziness, alterations of taste and smell

- Eye disorders

Not known: cataract, glaucoma, increased ocular pressure, blurred vision (see also 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

Reduction of growth velocity has been observed in children during a post-marketing clinical trial with NASACORT (see section 5.1)

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. Growth retardation has been reported in children receiving intranasal steroids.

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 is 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 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 and relief may be expected in 3 to 4 days. When NASACORT is prematurely discontinued symptoms may not recur for several days.

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

A one-year double-blind, placebo-controlled parallel group study in 298 treated pediatric patients (3 to 9 years of age) was conducted to assess the effect of NASACORT (once-daily dose of 110 micrograms) on growth velocity using stadiometry. From the primary analysis of evaluable patients (134 NASACORT and 133 placebo), the estimated growth velocity in the NASACORT group was 0.45 cm/year lower than that in the placebo group with 95% CI ranging between 0.11 to 0.78 cm/year lower than placebo. Difference between treatment groups started within 2 months of drug initiation. After stopping treatment during the 2-month follow-up period it was observed that the mean growth velocity in the treatment group returned to baseline (pre-treatment) values.

5.2 Pharmacokinetic properties

Single dose intranasal administration of 220 micrograms of NASACORT in 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. 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 actuation) 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 is contained in a 20 mL high density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit.
One bottle of NASACORT contains either 6.5 g or 16.5 g of suspension, providing 30 or 120 actuations respectively.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Ltd
T/A Sanofi
18 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA0540/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 1998

Date of last renewal: 19th January 2007

10 DATE OF REVISION OF THE TEXT

October 2017