SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nasacort Allergy 55 micrograms/dose Nasal Spray suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active component of Nasacort Allergy or Triamcinolone Nasal Spray is triamcinolone acetonide. Each bottle of Nasacort Allergy or Triamcinolone Nasal Spray contains 3.575 mg triamcinolone acetonide and provides at least 30 actuations each containing 55 micrograms of active compound after initial priming. (See Section 4.2)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal Spray suspension.
It is an unscented, thixotropic suspension of microcrystalline triamcinolone acetonide in an aqueous medium.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nasacort Allergy or Triamcinolone Nasal Spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis.

4.2 Posology and method of administration

Patients aged 18 years and over: The recommended 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). The minimum effective dose should be used to ensure continued control of symptoms.

Children: not recommended for children or adolescents under 18 years of age.

Medical advice should be sought if symptoms worsen or persist after 14 days treatment.

It is important to shake the bottle gently before each use.
Each actuation delivers 55 micrograms triamcinolone acetonide from the nasal actuator to the patient (estimated from *in vitro* testing) after an initial priming of 5 sprays until a fine mist is achieved. Nasacort Allergy or Triamcinolone Nasal Spray will remain adequately primed for 2 weeks. If the product is unused for more than 2 weeks, then it can be adequately re-primed 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 dust-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 dust-cap and the spray nozzle only* (pull off).

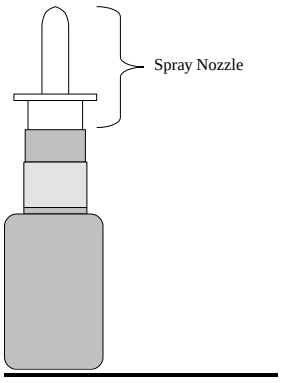
2. Soak the dust-cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.

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. Do not transfer any remaining suspension to another bottle.

4.3 Contraindications

Hypersensitivity to any of the ingredients of this preparation or an infection in the nose contraindicates its use.

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 or Triamcinolone Nasal Spray. Patients taking steroids should consult their doctor before using this product.

In clinical studies with Nasacort Allergy or Triamcinolone Nasal Spray 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 discontinuation of treatment with Nasacort Allergy or Triamcinolone Nasal Spray.

Because of the inhibitory effect of corticosteroids on wound healing, patients who have had recent nasal surgery or recent prolonged nose-bleeds or any other nasal problems should consult their doctor before using this product.

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.

This product should not be used for longer than 3 months without consulting a doctor.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

PREGNANCY

Nasacort Allergy or Triamcinolone Nasal Spray should only be used in pregnancy on medical advice. There are no adequate and well-controlled studies in pregnant women with Nasacort Allergy or Triamcinolone Nasal Spray. Because animal studies indicate a teratogenic effect, typical of corticosteroids, Nasacort Allergy or Triamcinolone Nasal Spray should not be administered during pregnancy unless the therapeutic benefit to the mother is considered to outweigh the risk to the foetus/baby. (See Section 5.3 Preclinical Safety Data)

LACTATION

Nasacort Allergy or Triamcinolone Nasal Spray should only be used in lactation on medical advice. It is not known whether triamcinolone acetonide is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be exercised when Nasacort Allergy or Triamcinolone Nasal Spray is administered to nursing women; therefore, the therapeutic benefit to the mother should outweigh any potential risk to the baby.

4.7 Effects on ability to drive and use machines

Nasacort Allergy or Triamcinolone Nasal Spray has no known effect on the ability to drive and operate machines.

4.8 Undesirable effects

The adverse events reported in clinical trials with Nasacort Allergy or Triamcinolone Nasal Spray most commonly involved the mucous membranes of the nose and throat.

The following frequency rating has been used, when applicable:
Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1 and < 1%; Rare ≥ 0.01 and < 0.1%; Very rare < 0.01% and not known (frequency cannot be estimated from available data).
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

The most frequent adverse reactions in adults 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 and alterations of taste and smell

- Eye disorders

Not known: cataract, glaucoma, increased ocular pressure

- 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Like any other nasally administered corticosteroid, acute overdosing with Nasacort Allergy or Triamcinolone Nasal Spray 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: nasal corticosteroid, ATC code: R 01 AD
Triamcinolone acetonide is a more potent derivative of triamcinolone and is approximately 8 times more potent than prednisone. Although the precise mechanism of corticosteroid anti-allergic action is unknown, corticosteroids are very effective in the treatment of allergic diseases in man.

Nasacort Allergy or Triamcinolone Nasal Spray 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 or Triamcinolone Nasal Spray and relief may be expected in 3 to 4 days. When Nasacort Allergy or Triamcinolone Nasal Spray is prematurely discontinued symptoms may not recur for several days.

In clinical studies performed in adults and children at doses up to 440 mcg/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 Allergy or Triamcinolone Nasal Spray in normal adult subjects and in adult patients with allergic rhinitis demonstrated minimal 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 or Triamcinolone Nasal Spray. 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 the effects typical of glucocorticosteroids were observed

Like other corticosteroids, triamcinolone acetonide has been shown to be teratogenic in rats and rabbits. Teratogenic effects which occurred in the rat and in the rabbit included 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
- carmellose sodium (Avicel CL-611),
- polysorbate 80,
- purified water,
- anhydrous glucose
- benzalkonium chloride
- edetate sodium
- hydrochloric acid or sodium hydroxide (for pH adjustment).

6.2 Incompatibilities

None known.

6.3 Shelf life

The shelf-life of Nasacort Allergy or Triamcinolone Nasal Spray is 24 months. The shelf life after the bottle is first opened is 1 month.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Nasacort Allergy or Triamcinolone Nasal Spray is contained in a 20 ml high density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit. Each bottle of Nasacort Allergy or Triamcinolone Nasal Spray contains 6.5 g of suspension and provides at least 30 actuations.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Aventis Pharma Limited
One Onslow Street
Guildford
Surrey
GU1 4YS
UK

or trading as

sanofi-aventis or Sanofi
One Onslow Street
Guildford
Surrey
GU1 4YS
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 04425/0605

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 October 1997

10 DATE OF REVISION OF THE TEXT

26 September 2013