Nasacort® AQ
Nasal Spray Suspension
Triamcinolone acetonide

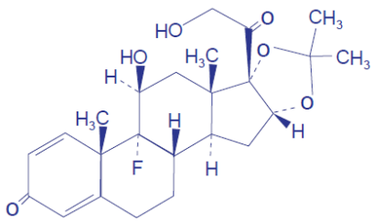
55 micrograms

SANOFI

Nasacort® AQ
[na' za-cort]
(triamcinolone acetonide)
Nasal Spray
For intranasal use only.
Shake Well Before Using

DESCRIPTION

Triamcinolone acetonide, USP, the active ingredient in **Nasacort® AQ** Nasal Spray, is a corticosteroid with a molecular weight of 434.51 and with the chemical designation 9-Fluoro-11ß,16 α,17,21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17- acetal with acetone ($C_{24}H_{31}FO6$).



Nasacort AQ Nasal Spray is an unscented, thixotropic, water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium. Microcrystalline cellulose, carboxymethylcellulose sodium, polysorbate 80, dextrose, benzalkonium chloride, and edetate disodium are contained in this aqueous medium; hydrochloric acid or sodium hydroxide may be added to adjust the pH to a target of 5.0 within a range of 4.5 and 6.0.
Each actuation delivers 55 mcg triamcinolone acetonide from the nasal actuator after an initial priming of 5 sprays. It will remain adequately primed for 2 weeks. If the product is not used for more than 2 weeks, then it can be adequately reprimed with one spray. The contents of one 6.5 gram bottle provide 30 actuations, and the contents of one 16.5 gram bottle provide 120 actuations. **After either 30 actuations or 120 actuations, the amount of triamcinolone acetonide delivered per actuation may not be consistent and the unit should be discarded.** Each 30 actuation bottle contains 3.575 mg of triamcinolone acetonide and each 120 actuation bottle contains 9.075 mg of triamcinolone acetonide.
In the Information for Patients, patients are provided with a checkoff form to track usage.

INDICATIONS AND USAGE

Nasacort AQ Nasal Spray is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 4 years of age and older.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of this preparation contraindicates its use.

SPECIAL WARNINGS AND PRECAUTION 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, long term use may cause oedema of the nasal mucosa.

Paediatric population
NASACORT is not recommended for use in children under 4 years of age.
Reduction in growth velocity has been reported in children receiving nasal corticosteroids, including NASACORT at licensed doses. See section pharmacodynamic .

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. The long-term effects of reduction in growth velocity associated with nasal corticosteroids, including the impact on final adult height are unknown. In addition, consideration should be given to referring the patient to a paediatric specialist, especially for children under the age of 6 years this is strongly recommended.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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.

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.

SG/NAS/0622/SmPC1121

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

ADVERSE REACTIONS

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 ≥1/10; Common ≥1/100 and <1/10; Uncommon ≥ 1/1,000 and < 1/100; Rare ≥ 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: *chorioretinopathy,* cataract, glaucoma, increased ocular pressure, blurred vision.
• 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 Pharmacodynamic properties)
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.

DOSAGE AND ADMINISTRATION

Recommended Doses: *Adults and Children 12 years of age and older:* The recommended starting and maximum dose is 220 mcg per day as two sprays in each nostril once daily.
Children 4 to 12 years of age: The recommended starting dose is 110 mcg per day given as one spray in each nostril once daily.
The maximum recommended dose is 220 mcg per day as two sprays per nostril once daily.
Nasacort AQ Nasal Spray is not recommended for children under 4 years of age since adequate numbers of patients have not been studied in this age group.
Individualization of Dosage: It is always desirable to titrate an individual patient to the minimum effective dose to reduce the possibility of side effects. In adults, when the maximum benefit has been achieved and symptoms have been controlled, reducing the dose to 110 mcg per day (one spray in each nostril once a day) has been shown to be effective in maintaining control of the allergic rhinitis symptoms in patients who were initially controlled at 220 mcg/day.
In children four to twelve years of age, the recommended starting dose is 110 mcg per day given as one spray in each nostril once daily. The maximum recommended daily dose in children 4 to 12 years of age is 220 mcg per day (two sprays in each nostril once daily). Some patients who do not achieve maximum symptom control at a dose of 110 mcg per day may benefit from a dose of 220 mcg given as two sprays in each nostril once daily. The minimum effective dose should be used to ensure continued control of symptoms. Once symptoms are controlled, pediatric patients may be able to be maintained on 110 mcg per day (1 spray in each nostril once daily).
An improvement in some patient symptoms may be seen within the first day of treatment, and generally, it takes one week of treatment to reach maximum benefit. Initial assessment for response should be made during this time frame and periodically until the patient's symptoms are stabilized. If adequate relief of symptoms has not been obtained after 3 weeks of treatment, Nasacort AQ Nasal Spray should be discontinued. (See **WARNINGS, PRECAUTIONS, Information for Patients, and ADVERSE REACTIONS**.)

Directions For Use: Illustrated Patient's Instructions for use accompany each package of Nasacort AQ Nasal Spray.

OVERDOSAGE

Like any other nasally administered corticosteroid, acute overdosing 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.

PHARMACOLOGICAL PROPERTIES

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 6 years of age and above at doses up to 440 mcg/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.

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.

Paediatric population
Following multiple doses intranasal administration of NASACORT, systemic exposures observed in paediatric patients 6 to 12 years of age were similar to those observed in adult patients.

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.

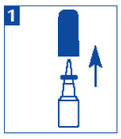
HOW SUPPLIED
Nasacort AQ Nasal Spray is a nonchlorofluorocarbon (non-CFC) containing metered-dose pump spray.
The contents of one 6.5 gram bottle provide 30 actuations, and the contents of one 16.5 gram bottle provide 120 actuations. The bottle should be discarded when the labeled number of actuations have been reached even though the bottle is not completely empty. It is supplied in a white high-density polyethylene container with a metered-dose pump unit, white nasal adapter, and patient instructions.

Keep out of reach of children.
Do not store above 30°C

Manufactured by: Recipharm HC Limited,
72 London Road – Holmes Chapel, Crewe, CW4 8BE - United Kingdom

INSTRUCTION OF USE

IMPORTANT: Please read these instructions carefully before using your NASACORT AQ Nasal Spray
How to use the spray
Before using your nasal spray, blow your nose gently to clear your nostrils.
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.



1. Preparing the bottle
- Remove the blue cover by pulling upwards
- Shake the bottle gently before use

2. If you are using the spray for the first time
- Hold the bottle upright
- Point the spray away from you while doing this
- Fill the pump with spray by pressing the nozzle downwards – this is called priming
- Press and release it 5 times
- Do this until a fine spray is produced
- The spray is now ready to use

3. Using the spray
- Close one nostril with your finger
- Hold the bottle upright and put the nozzle into the other nostril as far as is comfortable
- Breathe in gently through your nose with your mouth closed
- While you are doing this, press the nozzle to deliver one spray

4. Then breathe out through

5. Repeat steps 3 and 4 if you have to spray again in the same nostril and for the other nostril

6. After using the spray
- to keep the spray nozzle clean, wipe it carefully with a clean tissue or handkerchief after each use
- replace the cap over the nozzle

If the nasal spray has not been used for more than 2 weeks:
- It needs to be primed again, to fill the nozzle with the spray
- the nozzle should be pointed away from you while you are doing this
- to prime, spray into the air once before use
- always shake the bottle gently before use

Cleaning the spray
If the spray does not work, the nozzle may be blocked.
Never try to unblock it or enlarge the tiny spray hole with a pin or other sharp objects.
This is because it can stop the spray from working.

The nasal spray should be cleaned at least once a week. It can be cleaned more often if it gets blocked.
Instructions for cleaning the spray
1. Remove the cap

2. Gently pull off the spray nozzle only

3. Soak the cap and spray nozzle in warm water for a few minutes
4. Rinse under the cold running tap water
5. Shake or tap to remove any water that is left
6. Allow to dry in the air
7. Re-fit the spray nozzle
8. Prime the nasal spray until a fine mist is formed
9. Use as normal

The bottle should be discarded after 30 actuations or within one month (6.5g pack), or 120 actuations or within 2 months (16.5kg pack), of starting treatment. Any remaining suspension should not be transferred to another bottle.

Date of revision: Jun 2022 (SmPC Nov 2021)