NASACORT AQ Nasal Spray

Initial U.S. Approval: 1957

**INDICATIONS AND USAGE**

- NASACORT AQ Nasal Spray is a corticosteroid indicated for treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older. (1)

**DOSE AND ADMINISTRATION**

- Adults and adolescents ≥ 12 years: Starting and maximum dose is 220 mcg/day (two sprays in each nostril once daily). (2.1)
- Children 6 to 12 years of age: Starting dose is 110 mcg/day (one spray in each nostril once daily). Maximum dose is 220 mcg/day (two sprays per nostril once daily). (2.2)
- Children 2 to 5 years of age: Starting and maximum dose 110 mcg/day (one spray in each nostril once daily). (2.2)
- Priming/Use: For intranasal use only. Shake well before each use. Before using for the first time, release 5 sprays into the air away from the face. If the product is not used for more than 2 weeks, release 1 spray into the air before using. (2.3)

**DOSAGE FORMS AND STRENGTHS**

- Nasal Spray: 55 mcg triamcinolone acetonide in each spray. (3)

**CONTRAINDICATIONS**

- Do not administer to patients with history of hypersensitivity to triamcinolone acetonide or any ingredients of this product. (4)

**WARNINGS AND PRECAUTIONS**

**ADVERSE REACTIONS**

Most common adverse reactions (≥2% incidence) were pharyngitis, epistaxis, flu syndrome, cough increased, bronchitis, dyspnea, tooth disorder, headache, pharyngolaryngeal pain, nasopharyngitis, abdominal upper pain, diarrhea, and excretion. (6.1)

Other adverse reactions, including serious adverse reactions, have been reported. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-833-1610 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

**HOW SUPPLIED/STORAGE AND HANDLING**

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

**REVISED: 07/2013**

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NASACORT AQ safely and effectively. See full prescribing information for NASACORT AQ.

Nasacort® AQ (triamcinolone acetonide)

Nasal Spray

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**CONTRAINDICATIONS**

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**WARNINGS AND PRECAUTIONS**

- Epistaxis, nasal septal perforation, Candida albicans infection, impaired wound healing. Monitor patients periodically for signs of adverse effects on the nasal mucosa. Avoid use in patients with recent nasal septal ulcers, nasal surgery, or trauma. (5.1)
- Development of glaucoma or posterior subcapsular cataracts. Monitor patients closely with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts. (5.2)
- Potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or oral herpes simplex. More serious or even fatal course of chickenpox or measles in susceptible patients. Use caution in patient with the above because of the potential for worsening of these infections. (5.3)
- Hypercoricinism and adrenal suppression with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue NASACORT AQ Nasal Spray slowly. (5.4)
- Potential reduction in growth velocity in children. Monitor growth routinely in pediatric patients receiving NASACORT AQ Nasal Spray. (5.5, 8.4)

**ADVERSE REACTIONS**

Most common adverse reactions (≥2% incidence) were pharyngitis, epistaxis, flu syndrome, cough increased, bronchitis, dyspnea, tooth disorder, headache, pharyngolaryngeal pain, nasopharyngitis, abdominal upper pain, diarrhea, and excretion. (6.1)

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**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 USE IN SPECIFIC POPULATIONS
8 USE IN SPECIFIC POPULATIONS
9 PATIENT COUNSELING INFORMATION

**FULL PRESCRIBING INFORMATION**

1 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 2 years of age and older.

2 DOSAGE AND ADMINISTRATION

Administer NASACORT AQ Nasal Spray by the intranasal route only. Shake NASACORT AQ Nasal Spray well before each use.

2.1 Adults and Adolescents 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. Titrating an individual patient to the minimum effective dose to reduce the possibility of side effects. 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.

2.2 Children 2 to 12 Years of Age

Children 2 to 12 years of age: The recommended starting dose is 110 mcg per day given as one spray in each nostril once daily. Children not responding adequately to 110 mcg per day may use 220 mcg (2 sprays in each nostril) once daily. Once symptoms have been controlled, the dosage may be decreased to 110 mcg once daily [see WARNINGS AND PRECAUTIONS (5.3), USE IN SPECIFIC POPULATIONS (8.4) AND CLINICAL PHARMACOLOGY (12.2)].

Children 2 to 5 years of age: The recommended and maximum dose is 110 mcg per day given as one spray in each nostril once daily [see WARNINGS AND PRECAUTIONS (5.3), USE IN SPECIFIC POPULATIONS (8.4) AND CLINICAL PHARMACOLOGY (12.2)].

NASACORT AQ Nasal Spray is not recommended for children under 2 years of age.

2.3 Administration Information

Priming: Prime NASACORT AQ Nasal Spray before using for the first time by shaking the contents well and releasing 5 sprays into the air away from the face. If the product is not used for more than 2 weeks, release 1 spray into the air before using. (2.3)

3 DOSAGE FORMS AND STRENGTHS

- Nasal Spray: 55 mcg triamcinolone acetonide in each spray. (3)

4 CONTRAINDICATIONS

Do not administer to patients with history of hypersensitivity to triamcinolone acetonide or any ingredients of this product. (4)

5 WARNINGS AND PRECAUTIONS

5.1 Local Nasal Effects

5.2 Glaucoma and Cataracts

5.3 Immunosuppression

5.4 Hypothalamic-Pituitary-Adrenal Axis Effects

5.5 Effect on Growth

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

6.2 Post-Marketing Experience

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.3 Nursing Mothers

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed
NASACORT AQ Nasal Spray. Therefore, patients using NASACORT AQ Nasal Spray over several months or longer should be examined periodically for evidence of Candida infection or other signs of adverse effects on the nasal mucosa.

Impaired Wound Healing: Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal ulcers, surgery, or trauma should not use NASACORT AQ Nasal Spray until healing has occurred.

5.2 Glaucoma and Cataracts
Nasal and inhaled corticosteroids may result in the development of glaucoma and/or cataracts. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

5.3 Immunosuppression
Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In children or adults who have not had these diseases or have not been properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment is also not known. If exposed treatment to the risk factors for varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, varicella-zoster immune globulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information,). If chickenpox develops, treatment with antiviral agents may be considered.

Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; untreated local or systemic fungal or bacterial infections; systemic viral or parasitic infections, or ocular herpes simplex because of the potential for worsening of these infections.

5.4 Hypothalamic-Pituitary-Adrenal Axis Effects
Hypercortisolemia and Adrenal Suppression: When intranasal steroids are used at higher than recommended dosages or in susceptible individuals at recommended dosages, systemic corticosteroid effects such as hypercortisolemia and adrenal suppression may appear. If such changes occur, the dosage of NASACORT AQ Nasal Spray should be discontinued slowly, consistent with accepted procedures for discontinuing oral corticosteroid therapy. The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency, e.g., in addition, some patients may experience symptoms of cortisol withdrawal, e.g., joint and/or muscular pain, lassitude, and depression. Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical corticosteroids should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical conditions requiring long-term systemic corticosteroid treatment, rapid decreases in systemic corticosteroid dosages may cause a severe exacerbation of their symptoms.

5.5 Effect on Growth
Corticosteroids, including NASACORT AQ Nasal Spray, may cause a reduction in growth velocity when administered to susceptible pediatric patients. Monitor the growth routinely of pediatric patients receiving NASACORT AQ Nasal Spray. To minimize the systemic effects of intranasal corticosteroids, including NASACORT AQ Nasal Spray, titrate each patient’s dose to the lowest dosage that effectively controls his/her symptoms [see Use in Specific Populations (8.4)].

6. ADVERSE REACTIONS
Systemic and local corticosteroid use may result in the following:

- Epistaxis, Candida albicans infection, nasal septal perforation, impaired wound healing [see Warnings and Precautions (5.1)]
- Glaucoma and Cataracts [see Warnings and Precautions (5.2)]
- Immunosuppression [see Warnings and Precautions (5.3)]
- Hypothalamic-pituitary-adrenal (HPA) axis effects, including growth reduction [see Warnings and Precautions (5.4, 5.5), Use in Specific Populations (8.4) and Clinical Pharmacology (12.3)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In placebo-controlled, double-blind, and open-label clinical studies, 1483 adults and children 12 years and older received NASACORT AQ Nasal Spray. Monitor the growth routinely of pediatric patients receiving NASACORT AQ Nasal Spray. These patients were treated for an average duration of 51 days. In the controlled trials (2-5 weeks duration) from which the following average adverse reaction data are derived, 1394 patients were treated with NASACORT AQ Nasal Spray for an average of 19 days. In a long-term, open-label study, 172 patients received treatment for an average duration of 286 days. Adverse reactions from 12 studies in adults and adolescent patients 12 to 17 years of age receiving NASACORT AQ Nasal Spray 27.5 mcg to 440 mcg once daily are summarized in Table 1.

In clinical trials, nasal septum perforation was reported in one adult patient who received NASACORT AQ Nasal Spray. Therefore, patients using NASACORT AQ Nasal Spray over several months or longer should be examined periodically for evidence of Candida infection or other signs of adverse effects on the nasal mucosa.

A total of 802 children 6 to 12 years of age were studied in 3 double-blind, placebo-controlled clinical trials. Of these, 172 received 110 mcg/day and 207 received 220 mcg/day of NASACORT AQ Nasal Spray for two, six, or twelve weeks. The longest average durations of treatment for patients receiving 110 mcg/day and 220 mcg/day were 76 days and 80 days, respectively. One percent of patients treated with NASACORT AQ were discontinued due to adverse events. No patient receiving 110 mcg/day and one patient receiving 220 mcg/day discontinued due to a serious adverse event. A similar adverse reaction profile was observed in pediatric patients 6–12 years of age as compared to adolescents and adults with the exception of epistaxis which occurred in less than 2% of the children studied. Adverse reactions from 2 studies in children 4 to 12 years of age receiving NASACORT AQ Nasal Spray 110 mcg once daily are summarized in Table 2.

Table 2 - Adverse drug reactions > 2% and greater than placebo with NASACORT AQ Nasal Spray 110 mcg treatment in studies in children 4 to 12 years of age

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>Placebo (N=857)</th>
<th>NASACORT AQ 110 mcg (N=857)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>0.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>0.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Cough increased</td>
<td>2.5</td>
<td>4.7</td>
</tr>
</tbody>
</table>

Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; untreated local or systemic fungal or bacterial infections; systemic viral or parasitic infections, or ocular herpes simplex because of the potential for worsening of these infections.

In addition to the adverse drug reactions reported during clinical studies and listed above, the following adverse reactions have been identified during post-approval use of NASACORT AQ Nasal Spray. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Reactions that have been reported during post-marketing experience include: nasal discomfort and congestion, sneezing, alterations of taste and smell, nausea, insomnia, dizziness, fatigue, dyspepsia, decreased blood cortisol, cataract, glaucoma, increased ocular pressure, pruritus, rash, and hyper-sensitivity.

8. USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C
There are no adequate and well-controlled studies of NASACORT AQ Nasal Spray in pregnant women. Teratogenic effects in rats was teratogenic in rats, rabbits, and monkeys. NASACORT AQ Nasal Spray, like other corticosteroids, should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Since their introduction, experience with oral corticosteroids in pharmacologic doses suggests that rodents are more prone to teratogenic effects from corticosteroids than humans. In addition, because there is a natural increase in glucocorticoid production during pregnancy, most women will require a lower exogenous corticosteroid dose and many will not need corticosteroid treatment during pregnancy.

In reproduction studies in rats and rabbits, triamcinolone acetonide administered by inhalation produced cleft palate and/or internal hydrocephaly and axial skeletal defects at exposures less than and not 2 times, respectively, the maximum recommended daily intranasal dose in adults on a mcg/m² basis. In a monkey reproduction study, triamcinolone acetonide administered by inhalation produced cranial malformations at an exposure approximately 37 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis.

8.3 Nursing Mothers
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 AQ Nasal Spray is administered to nursing women.

8.4 Pediatric Use
The safety and effectiveness of NASACORT AQ Nasal Spray has been evaluated in 464 children 2 to 5 years of age, 516 children 6 to 12 years of age, and 176 adolescents 12 to 17 years of age [see Clinical Studies (14)]. The safety and effectiveness of NASACORT AQ Nasal Spray in children below 2 years of age have not been established.

Clinical controlled studies have shown that intranasal corticosteroids may cause a reduction in growth velocity in pediatric patients. This effect has been observed in the absence of laboratory evidence of HPA axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than the commonly used tests of HPA axis function. The long-term effects of reduction in growth velocity associated with intranasal corticosteroids, including the impact on final adult height are unknown. The potential for “catch-up” growth following discontinuation of treatment with intranasal corticosteroids has not been adequately studied. The growth of pediatric
patients receiving intranasal corticosteroids, including NASACORT AQ Nasal Spray, should be monitored routinely (e.g., via pituitary function). The potential growth effects of treatment should be weighed against the clinical benefits obtained and the risks/benefits of treatment alternatives. To minimize the systemic effects of intranasal corticosteroids, including NASACORT AQ Nasal Spray, each patient's dose should be titrated to the lowest dosage that effectively controls his/her symptoms. The effect of NASACORT AQ Nasal Spray on growth velocity in children was assessed in a 12 month randomized, placebo-controlled study conducted in 299 prepubescent children aged 3 to 9 years (173 males, 126 females) with perennial allergic rhinitis. Treatment groups were NASACORT AQ 110 mcg once daily and placebo. Growth velocity was estimated for each patient using the slope of the linear regressions of height over time using observed data in the intent to treat population who had at least 3 height measurements after randomization. Growth velocities were significantly lower in the NASACORT AQ group compared to placebo, with a mean growth velocity of 6.09 cm/year in the placebo group and 5.65 cm/year in the NASACORT AQ treated group (difference from placebo -0.45 cm/year; 95% CI: -0.78, -0.11).

8.5 Geriatric Use
Clinical studies of NASACORT AQ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

OVERDOSAGE
Chronic overdose may result in signs/symptoms of hypercorticism [see Warnings and Precautions (5.4)]. There are no data on the effects of acute or chronic overdose with NASACORT AQ Nasal Spray. Because of local system bioavailability and an absence of acute drug-related systemic findings in clinical studies overdose is unlikely to require any therapy other than observation. Acute overdose involving the intranasal dosage form is unlikely in view of the total amount of active ingredient present and low bioavailability of triamcinolone acetonide. In the event that the entire contents of the bottle were administered all at once, either oral or nasal application, clinically significant systemic adverse events would most likely not result.

11 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-11b,17a-dihydroxy-16α,17α-dihydroxyprogren-4-ene-3,20-dione cyclic 16,17-acetal with acetone (C22H22FO5).

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Triamcinolone acetonide is a synthetic fluorinated corticosteroid with approximately 8 times the potency of prednisone in animal models of inflammation. Although the precise mechanism of corticosteroid anti-inflammatory action is unknown, corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eosinocids, leukotrienes, cytokines) involved in inflammation.

12.2 Pharmacodynamics
In order to determine if systemic absorption plays a role in the effect of NASACORT AQ Nasal Spray on allergic rhinitis symptoms, a two week double-blind, placebo-controlled clinical study was conducted comparing NASACORT AQ orally ingested triamcinolone acetonide, and placebo in 297 adult patients with seasonal allergic rhinitis. The study demonstrated that the therapeutic efficacy of NASACORT AQ Nasal Spray can be attributed to the topical effects of triamcinolone acetonide.

Adrenal Function: In order to evaluate the effects of systemic absorption on the Hypothalamic-Pituitary-Adrenal (HPA) axis, 4 clinical studies, each one in adults and in children 6-12 years of age, 2-5 years of age, and 2-11 years of age, were conducted. The adult clinical study compared 220 mcg or 440 mcg NASACORT AQ per day, or 10 mcg prednisone per day with placebo for 42 days. Adrenal response to a six-hour 250 mcg cosyntropin stimulation test showed that NASACORT AQ administered at doses of 220 mcg and 440 mcg had no statistically significant effect on HPA axis versus placebo. Conversely, oral prednisone at 10 mg/day significantly reduced the response to ACTH. A study evaluating plasma cortisol response thirty and sixty minutes after 250 mcg NASACORT AQ nasal spray was compared to placebo nasal spray. A subset of 24 children 6 to 11 years of age received a higher dose of 220 mcg of NASACORT AQ Nasal Spray. The Cmax and AUC0-∞ values were 1.4 ng/mL to 4.7 ng·hr/mL between doses of 110 mcg to 440 mcg in both pituitary and healthy volunteers. Plasma drug concentration was less than 0.06 ng/mL at 12 hours, and below the assay detection limit (the minimum LOQ of the assay was 0.025 ng/mL) at 24 hours. The average terminal half-life was 3.1 hours. The range of mean AUC∞ values was 1.4 ng·hr/mL to 4.7 ng·hr/mL between doses of 110 mcg to 440 mcg in both pituitary and healthy volunteers. No dose proportionality was observed in the normal adult subjects and in allergic rhinitis patients following single intranasal doses of 110 mcg or 220 mcg NASACORT AQ Nasal Spray. The Cmax and AUC0-∞ of the 440 mcg dose increased less than proportionally when compared to 110 and 220 mcg doses. NASACORT AQ contains a microcrystalline suspension of triamcinolone acetonide in a water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium. Microcrystalline cellulose, carbomethoxymethylcellulose sodium, polvidone B, 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.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
In a two-year study in rats, triamcinolone acetonide caused no treatment-related carcinogenicity at oral doses up to 1.0 mg/kg (less than the maximum recommended daily intranasal dose in adults and children 12 years and older with seasonal allergic rhinitis). In general, no treatment-related carcinogenicity at oral doses up to 3.0 mg/kg (less than the maximum recommended daily intranasal dose in adults and children on a mcg/m2 basis, respectively). No evidence of mutagenicity was detected from in vitro tests (a reverse mutation test in Salmonella bacteria and a forward mutation test in Chinese hamster ovary cells) conducted with triamcinolone acetonide. In male and female rats, triamcinolone acetonide caused no change in pregnancy rate or at oral doses up to 3.0 mg/kg (less than the maximum recommended daily intranasal dose in adults on a mcg/m2 basis). Triamcinolone acetonide caused increased fetal resorptions and stillbirths and decreases in pup weight and survival at doses of 5.0 mg/kg and above (less than the maximum recommended daily intranasal dose in adults on a mcg/m2 basis). At 1.0 mg/kg (less than the maximum recommended daily intranasal dose in adults on a mcg/m2 basis), it did not induce the above mentioned effects.

13.2 Animal Toxicology and/or Pharmacology
Triamcinolone acetonide was teratogenic in rats, rabbits, and monkeys. In rats, triamcinolone acetonide was teratogenic at an inhalation dose of 20 mcg/kg and above (approximately 3% of the maximum recommended daily intranasal dose of 220 mcg administered over 24 weeks). In rabbits, treatment-related fetal effects were observed at oral doses of 0.1 and 0.5 mg/kg (approximately the maximum recommended daily intranasal dose in adults on a mcg/m2 basis). Triamcinolone acetonide was teratogenic at an inhalation dose of 100 mcg/kg (approximately 1% of the maximum recommended daily intranasal dose in adults on a mcg/m2 basis). In monkeys, triamcinolone acetonide was teratogenic at an inhalation dose of 500 mcg/kg (approximately 1% of the maximum recommended daily intranasal dose in adults on a mcg/m2 basis). Dose-related teratogenic effects in rats and rabbits included cleft palate and/or internal hydrocephaly and axial skeletal defects, whereas the effects observed in the monkey were cranial malformations. Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully observed.

14 CLINICAL STUDIES
The safety and efficacy of NASACORT AQ Nasal Spray have been evaluated in 10 double-blind, placebo-controlled clinical studies of two- to four-weeks duration in adults and children 12 years and older with seasonal or perennial allergic rhinitis. The number of patients treated with NASACORT AQ Nasal Spray in these studies was 1256; of these patients, 675 were males and 591 were females. Overall, the results of these clinical studies in adults and children 12 years and older demonstrated that NASACORT AQ Nasal Spray 220 mcg once daily (2 sprays in each nostril), when compared to placebo, statistically significantly reduced symptoms of seasonal or perennial allergic rhinitis including sneezing, stuffiness, discharge, and itching.

The safety and efficacy of NASACORT AQ Nasal Spray, at doses of 110 mcg or 220 mcg once daily, have also been adequately studied in two double-blind, placebo-controlled studies of two- and twelve-weeks duration in children ages 6 through 12 years with seasonal and perennial allergic rhinitis. The study included 341 males and 177 females. NASACORT AQ administered at either dose resulted in statistically significant reductions in the severity of nasal symptoms of allergic rhinitis. The safety and efficacy of NASACORT AQ Nasal Spray in children 2 to 5 years of age with perennial allergic rhinitis with or without seasonal allergic rhinitis was studied in a single 4 week double-blind, placebo-controlled clinical study with a parallel-dose design study in the United States. The study included 484 patients (266 males and 198 females) 2 to 5 years of age who received at least one dose of study medication (233 placebo, 231 NASACORT AQ 110 mcg once daily). Efficacy was determined over a four-week double-blind, placebo-controlled treatment period and was based on a weighted average of total symptom score (TSS), nasal congestion, itching, rhinorrhea, and sneezing on a 0–3 categorical severity scale (0=absent, 1=mild, 2=moderate, and 3=severe) once daily. Reflective scoring (rTSS) required recording symptom severity over the previous 24 hours; the instantaneous scoring (iTSS) required recording symptom severity at the time just prior to dosing. Baseline symptom severity was comparable between NASACORT AQ and placebo respectively, for iTNSS (7.52, 7.61) and rTNSS (7.96, 7.87). While the severity at the time just prior to dosing. Baseline symptom severity was comparable between NASACORT AQ and placebo respectively, for iTNSS (7.52, 7.61) and rTNSS (7.96, 7.87). While the
In the Patient Package Information, patients are provided with a check-off form to track usage of 5 sprays.

**IMPORTANT:**

NASACORT AQ Nasal Spray, 55 mcg per spray, is supplied in a white high-density polyethylene container with a metered-dose pump unit, white nasal adapter, and adapter (NDC 0075-1506-16).

The contents of one 16.5 gram bottle provide 120 actuations. After 120 actuations, the amount of triamcinolone acetonide delivered per actuation may not be consistent and the unit should be discarded. Each actuation delivers 55 mcg triamcinolone acetonide from the nasal actuator after an initial priming of 5 sprays (see Dosage and Administration Information [2.3]).

In the Patient Package Information, patients are provided with a check-off form to track usage (see Patient Counseling Information [17]).

Keep out of reach of children.

16.2 Storage

Store at Controlled Room Temperature, 20 to 25°C (68 to 77°F).

**17. PATIENT COUNSELING INFORMATION**

See FDA-approved patient labeling (Patient Information and Instructions for Use).

17.1 Local Nasal Effects

Patients should be informed that treatment with NASACORT AQ Nasal Spray may lead to adverse reactions, which include epistaxis and nasal ulceration. Candida infection may also occur with treatment with NASACORT AQ Nasal Spray. In addition, nasal corticosteroids are associated with nasal septal perforation and impaired wound healing. Patients who have experienced recent nasal ulcers, nasal surgery, or nasal trauma should not use NASACORT AQ Nasal Spray until healing has occurred (see Warnings and Precautions [5.1]).

17.2 Cataracts and Glaucoma

Patients should be informed that glaucoma and cataracts are associated with nasal and inhaled corticosteroid use. Patients should inform his/her health care provider if a change in vision is noted while using NASACORT AQ Nasal Spray (see Warnings and Precautions [5.2]).

17.3 Immunosuppression

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to consult their physician without delay. Patients should be informed of potential worsening of existing tuberculosis, fungal, bacterial, viral or parasitic infections, or ocular herpes simplex (see Warnings and Precautions [5.3]).

17.4 Effect on Growth

Patients should be advised that NASACORT AQ Nasal Spray may slow growth in children. A child taking NASACORT AQ Nasal Spray should have his/her growth checked regularly (see Warnings and Precautions [5.5] and Pediatric Use [8.4]).

17.5 Use Daily for Best Effect

Patients should use NASACORT AQ Nasal Spray on a regular once-daily basis for optimal effect. It is also important to shake the bottle well before each use. Do not blow your nose for 15 minutes after using the spray. NASACORT AQ Nasal Spray, like other corticosteroids, does not have an immediate effect on rhinitis symptoms. Although improvement in some patient symptoms may be seen within the first day of treatment, maximum benefit may not be reached for up to one week. The patient should not increase the prescribed dosage but should contact the physician if symptoms do not improve or if the condition worsens.

17.6 Keep Spray Out of Eyes

Patients should be informed to avoid spraying NASACORT AQ Nasal Spray in their eyes.

**IMPORTANT:** Please read these instructions carefully before using your NASACORT™ AQ Nasal Spray

**Patient Information**

Nasacort® AQ (na’-za-cort) (triamcinolone acetonide) Nasal Spray

**These instructions provide important information about Nasacort AQ. Ask your healthcare provider or pharmacist if you have any questions. Important:** For use as a nasal spray only.

**What is Nasacort AQ?**

Nasacort® AQ Nasal Spray is a prescription medicine called a corticosteroid used to treat nasal symptoms of seasonal and year-around allergies in adults and children 2 years of age and older. When Nasacort AQ is sprayed in your nose, this medicine helps to lessen the symptoms of sneezing, runny nose, nasal itching and stuffy nose. Nasacort AQ is not for children under the age of 2 years.

Who should use Nasacort AQ?

Do not use Nasacort AQ if you have had a reaction to triamcinolone acetonide or to any of the other ingredients in Nasacort AQ. See the end of this leaflet for a complete list of ingredients in Nasacort AQ.

**What should I tell my healthcare provider before using Nasacort AQ?**

Tell your healthcare provider if you are:

- pregnant or planning to become pregnant
- breastfeeding
- exposed to chickenpox or measles
- feeling unwell or have any symptoms that you do not understand

Tell your healthcare provider about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

How do I use Nasacort AQ?

- Use Nasacort AQ exactly as your healthcare provider tells you.
- You will get the best results if you use Nasacort AQ regularly and without missing a dose. Do not take extra doses.
- Nasacort AQ should be used as a nasal spray only. Do not spray it in your eyes or mouth.
- Your healthcare provider will tell you how and when to use Nasacort AQ. Do not use more Nasacort AQ or take it more often than your healthcare provider tells you.
- The prescription label will usually tell you how many sprays to take and how often. If it does not or if you are unsure, ask your healthcare provider or pharmacist.

For people aged 12 years and older, the usual dose is 2 sprays in each nostril, one time each day.

- For children aged 6 to 12 years, the usual dose is 1 spray in each nostril, one time each day.
- Your healthcare provider may tell you to take 2 sprays in each nostril one time each day.
- For children aged 2 to 5 years, the usual dose is 1 spray in each nostril, one time each day.
- An adult should help a young child use this medicine.
- Do not stop taking Nasacort AQ without telling your healthcare provider. Before you throw away Nasacort AQ, talk to your healthcare provider to see if you need another prescription. If your healthcare provider tells you to continue using Nasacort AQ, throw away the empty or expired bottle and use a new bottle of Nasacort AQ.

- For detailed instructions, see the “Instructions for Use” at the end of this leaflet.
- Some symptoms may get better on the first day of treatment. It generally takes one week of use to feel the most benefit.
- Protect your eyes from the spray. If you get the spray in your eyes, rinse your eyes well with water.
- If your symptoms do not improve, or if they become worse, contact your healthcare provider.
- Tell your healthcare provider if you have irritation, burning or stinging inside your nose that does not go away when using Nasacort AQ.

**What are the possible side effects of Nasacort AQ?**

Common side effects of Nasacort AQ include:

- Sore throat, headache, and nosebleeds. If you have an increase in nosebleeds after using Nasacort AQ or the inside of your nose hurts, contact your healthcare provider.
- What are the other risks of using Nasacort AQ?

**Hole in the cartilage inside the nose (nasal septal perforation).** Tell your healthcare provider if you have a whistling sound from your nose when you breathe.

**Fungal infection in your nose.**

- Slow wound healing. You should not use Nasacort AQ until your nose has healed if you have a sore in your nose, if you have had surgery on your nose, or if your nose has been injured.
- Eye problems such as glaucoma and cataracts. Tell your healthcare provider if you have a change in vision or have a history of increased intraocular pressure, glaucoma, or cataracts.
- Immune system problems that may increase your risk of infections. You are more likely to get infections if you take medicines that weaken your body’s ability to fight infections. Avoid contact with people who have contagious diseases such as chickenpox or measles while using Nasacort AQ.
- Symptoms of infection may include fever, pain, aches, chills, feeling tired, nausea and vomiting.

**Effect on how fast children grow.** Nasacort AQ may cause your child’s growth to slow down. If your child is taking Nasacort AQ, your healthcare provider will need to regularly check the height of your child and adjust the dose as appropriate.

These are not all the possible side effects of Nasacort AQ. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

**Instructions for Use**

Read these instructions carefully before using your Nasacort AQ.

Before using the spray pump bottle:

1. Pull the blue cover and remove the clip from the spray pump unit. See figure A.

2. Shake the spray pump bottle before each use.

Priming the Spray Pump Bottle

3. Before using the spray pump bottle for the first time, it must be primed. To prime, put your thumb on the bottom of the bottle and your index and middle fingers on the “shoulders” of the bottle, and hold it upright. See figure B.

4. Point the bottle away from your eyes. Push the bottle up with your thumb and against your two fingers firmly and quickly until a fine spray appears. Do this pumping action 5 times. Now your spray pump bottle is primed and ready for use. A fine mist can only be made by a rapid and firm pumping action.

5. Repeat priming the pump, if it has not been used for more than 2 weeks. To reprim, shake the spray pump bottle and pump it just one time. Now the spray pump bottle is reprimed.

6. Pull the blue cover and remove the clip from the spray pump unit. See figure A.

7. Shake the spray pump bottle before each use.

**Prime the Spray Pump Bottle**

8. Before using the spray pump bottle for the first time, it must be primed. To prime, put your thumb on the bottom of the bottle and your index and middle fingers on the “shoulders” of the bottle, and hold it upright. See figure B.

9. Point the bottle away from your eyes. Push the bottle up with your thumb and against your two fingers firmly and quickly until a fine spray appears. Do this pumping action 5 times. Now your spray pump bottle is primed and ready for use. A fine mist can only be made by a rapid and firm pumping action.

10. To reprim, shake the spray pump bottle and pump it just one time. Now the spray pump bottle is reprimed.

**Prime the Spray Pump Bottle**

11. Before using the spray pump bottle for the first time, it must be primed. To prime, put your thumb on the bottom of the bottle and your index and middle fingers on the “shoulders” of the bottle, and hold it upright. See figure B.

12. Point the bottle away from your eyes. Push the bottle up with your thumb and against your two fingers firmly and quickly until a fine spray appears. Do this pumping action 5 times. Now your spray pump bottle is primed and ready for use. A fine mist can only be made by a rapid and firm pumping action.

13. To reprim, shake the spray pump bottle and pump it just one time. Now the spray pump bottle is reprimed.
Using the spray:

6. Gently blow your nose to clear it, if needed. For small children, be sure to help them gently blow their nose, as much as possible.
7. Pull off the blue cover and clip as shown in figure C. Shake the spray pump well.

8. Hold the spray pump firmly, with the index and middle finger on either side of the spray tip. Place your thumb on the bottom of the bottle. Be careful so that your fingers will not slip off the spray pump as you spray inside your nose. See figure D.

9. Put the spray tip into one side of your nose. The tip should not reach far into the nose. Rest the side of your index finger against your upper lip. Tip your head back a little and aim the spray toward the back of your nose. See figure E.

10. Press against the other side of your nose with your finger so the nostril is closed. Pump the spray bottle by pushing on the bottom of the bottle with your thumb firmly and quickly for the full dose of medicine. Sniff gently at the same time to help the medicine get to the back of your nose. See figure F. Repeat this step for the other side.

11. Repeat steps 8, 9 and 10 if your healthcare provider tells you to use more than one spray in each nostril.
12. Do not blow your nose for 15 minutes after using the spray.
13. After use, wipe the nozzle on the spray bottle with a clean tissue, and replace the blue cover.
14. Keep the cover and the clip on the spray pump bottle when not in use.

Cleaning the spray pump bottle:

15. To clean the spray pump bottle, remove the blue cover and the spray nozzle only. Soak the cover and spray nozzle in warm water for a few minutes, and then rinse under cold water. See figure G.

16. Shake or tap off the excess water and allow to air dry. Once the cap and spray nozzle are dry, put the nozzle back onto the bottle, and prime the bottle as necessary until a fine mist is made. Use the spray as directed by your healthcare provider.

If the spray bottle does not work:

The hole in the tip of the nozzle may be blocked. Never try to unblock the spray hole or enlarge it with a pin or other sharp object. This will make the spray mechanism not work correctly. Changing the size of the opening can change the amount of medicine you or your child will receive. This could cause an overdose of the medicine. To clean nasal spray pump bottle, refer to Step 15.

Important information

Repriming the spray pump is only necessary when it has not been used for more than 2 weeks. To reprime, shake the bottle and only pump the spray bottle one time. Do not reprime if you use the spray more often than every two weeks.

Each Nasacort AQ bottle contains 120 doses of medicine plus a little extra for priming the pump. A check-off chart is included with your Nasacort AQ to help you keep track of the number of sprays. This will help make sure that you receive 120 sprays of Nasacort AQ.

How should I store Nasacort AQ?

- Store Nasacort AQ between 68° to 77°F (20° to 25° C).
- After using 121 sprays, throw the medicine away, as directed by your healthcare provider, even if the bottle is not empty. You may not get enough medicine if you use the bottle after 120 sprays.
- Keep Nasacort and all medicines out of the reach of children. General information about the safe and effective use of Nasacort AQ. Medicines are sometimes prescribed for conditions that are not mentioned in patient information. Do not use Nasacort AQ for a condition for which it was not prescribed. Do not give Nasacort AQ to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about Nasacort AQ. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Nasacort AQ that is written for health professionals.
For more information call 1-800-633-1610.

What are the ingredients in Nasacort AQ?

Active ingredient: triamcinolone acetonide
Inactive ingredients: 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.