Nasacort AQ
Triamcinolone acetonide

55 micrograms/dose
intranasal route

SANOFI

120 sprays each delivering 55 micrograms triamcinolone acetonide

This package insert is continually updated; please read carefully before using a new pack, in case of any question, please contact your physician or pharmacist.

NASACORT® AQ Nasal spray

Composition
Active ingredient: triamcinolone acetonide. Each actuation delivers 55 micrograms triamcinolone acetonide.
Excipients: microcrystalline cellulose, carmellose sodium (Avicel CL-611), polysorbate 80, purified water, anhydrous glucose, benzalkonium chloride, disodium edentate, hydrochloride acid or sodium hydroxide (for pH adjustment).

Nasacort AQ Nasal spray suspension is supplied as an unscented, thixotropic suspension of microcrystalline triamcinolone acetonide in an aqueous medium.
Nasacort AQ Nasal spray suspension has a target pH of 5.0 within a range 4.5 – 6.0.

Pharmacological Properties

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 antiallergic action is unknown, corticosteroids are very effective in the treatment of allergic diseases in man. NASACORT AQ does not have an intermediate effect on allergic sign and symptoms. An improvement in some patients symptoms may be seen within the first day of treatment with NASACORT AQ and relief may be expected in 3 or 4 days. When NASACORT AQ 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 Hypothalmic-Pituitary-Adrenal (HPA) axis has been observed.

2. Pharmacokinetic Properties
Single dose intranasal administration of 220 micrograms of NASACORT AQ in normal adult subjects and in adult patients with allergic rhinitis demonstrated low absorption on 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 AQ.

3. Pre-clinical 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 mutagenecity was detected in *in-vitro* gene mutation tests.

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

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

Posology and Method of Administration
NASACORT AQ is for nasal use only.

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).

Special Warning and Special 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 AQ.

In clinical studies with NASACORT AQ 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 discontinuance of treatment with NASACORT AQ.

Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, NASACORT AQ 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).

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.

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

Reduction in growth velocity has been reported in children receiving nasal corticosteroids at licensed doses
It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed 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.

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.

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 outweight the potential risk to the foetus/baby.

Effects on Ability to Drive and Use Machines
NASACORT AQ has no known effect on the ability to drive and operate machines.

Undesirable Effects
The adverse events reported in clinical trials with NASACORT AQ 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 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

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

Overdose
Like any other nasally administered corticosteroid, acute overdosing with NASACORT AQ 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.

Interaction with other Medicinal Products and other Forms of Interaction
No interactions with other medicaments are known.

Contra-Indications
Hypersensitivity to the active substance or to any of the excipients.

Storage
Do not store above 30°C.

The bottle should be discarded after 120 actuations or within 2 months of starting treatment.

Do not transfer any remaining suspension to another bottle.
Keep out of reach of children.

Presentation
A high density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit.

Each bottle of NASACORT AQ Nasal spray contains 16.5 g of suspension, with 9.075 mg triamcinolone acetonide, and provide at least 120 actuations.

Reg. No. DKI0188400756A1

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

Imported by:
PT Aventis Pharma, Jakarta, Indonesia

ON MEDICAL PRESCRIPTION ONLY

HARUS DENGAN RESEP DOKTER

550366

SANOFI

Regional Packaging Unit (RPU)

GENERAL

Code	: 550366
Update	: 25/06/2020 - Ver 1
Local Code SCM	: N/A
Current Item Code	: 546052/547056/549491
Product/Item Type	: NASACORT AQ 55 ug INSERT
Pack Size	
Box of	: 00s
Blister	: 0 × 00
Country	: INDONESIA
Languages	: English
Market Barcode	: N/A
Artwork By	: Ana Novillas
Revised By	: Emerra AMIHAN / E. PEQUERO
Plant	: REC - SG

TECHNICAL

Format	: 148 × 180 mm
Plant Barcode	: N/A
Color/s	: 1
	Pantone Reflex Blue CVC
Font/s	: Ocean Sans Pro SAN: Light, Bold
Size	: 7 pts.
Technical Plans	: N/A

DISETUJUI OLEH BPOM : 27/04/2021

ID : EREG100022VR12000248

Nasacort AQ
triamcinolone acetonide

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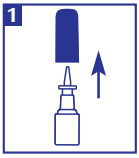
Preparation and handling
Nasacort AQ Nasal Spray is for nasal administration only.

IMPORTANT: Please read these instruction carefully before using your Nasacort AQ Nasal Spray

Prior to use

1. Pull the cap and clip off the spray pump unit. Do not attempt to enlarge the tiny hole in the spray tip. If the actuator has come off pump stem, re-insert system in actuator.
2. Shake the spray pump unit



Preparing to use

3. Prior to first use, the spray pump unit should be primed. To prime, put two fingers on the "shoulders" of the bottle. Push the bottle FIRMLY and QUICKLY for a full-stroke with 5 actuations until a fine mist is produced. It will then remained adequately primed for 2 weeks. If not used for more than 2 weeks, repriming can be achieved with 1 actuation. Hold the nozzle pointing away from you while you are doing this.

To use

4. Gently blow nose to clean nostrils, if needed.
5. Hold spray pump unit FIRMLY as shown with the index and middle finger on either side of the spray tip and thumb on bottom of the bottle. Rest back of index finger against upper lip.
6. Put the spray tip into one nostrill (tip should not reach far into the nose). Bend head forward so spray will aim toward the back of the nose.
7. Point tip straight back into nose. Close the other nostril with finger. Pump spray unit by pushing the bottle with thumb FIRMLY and QUICKLY for a full-stroke actuation and sniff gently at the same time. Repeat procedure for the other nostril.

8. Repeat steps 5, 6 and 7 if instructed to use more than one spray per nostril.
9. Avoid blowing nose for 15 minutes following dosing. For best result the product should be used regularly.

After using
Wipe the nozzle carefully with a clean tissue or hankerchief, and replace the cap. If the spray does not work and it may be blocked, clean it as described below. 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 if it gets blocked.

Cleaning the spray

1. Remove the cap and the spray nozzle only (see the graph below)

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

3. Shake off or tap off the excess of water and allow air-drying.
4. Re-fit the spray nozzle
5. Prime the unit as necessary until a fine mist is produced and use as normal.
6. Keep the cover and the clip on the spray pump unit when in use

Storage
Do not store above 30°C
Use within 2 months after first opening the nasal spray and then, discarded.
Any remaining suspension should not be transferred to another bottle.
Keep out of the reach of children.

Expiry date
Do not use later than the date of expiry indicated on the outer packaging.

Presentation
White high-density (HDPE) bottles, fitted with a metered-dose spray pump unit.
Each bottle of Nasacort AQ Nasal spray contains 16.5 g of suspension, with 9.075 mg triamcinolone acetonide, and provide at least 120 actuations.

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Nasacort® AQ
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SANOFI

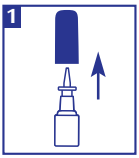
PETUNJUK PENGGUNAAN

NASACORT AQ Nasal Spray hanya digunakan untuk semprot hidung.

PENTING: Bacalah petunjuk ini dengan hati-hati sebelum anda menggunakan semprot hidung NASACORT AQ.

Sebelum Penggunaan

1. Tariklah penutup dari unit pompa Semprot. Jangan mencoba membesarkan lubang kecil pada ujung semprotan. Jika actuator telah terlepas dari pompa, masukkan kembali pompa kedalam actuator.
2. Kocok unit pompa semprot



Persiapan untuk penggunaan

3. Sebelum penggunaan pertama, pompa semprot harus terisi. Untuk mengisi, letakkan dua jari pada "bahu" botol. Tekan botol dengan ibu jari SECUKUPNYA dan secara CEPAT untuk menyemprotkan semprotan secara penuh sebanyak lima kali hingga menghasilkan semprotan obat yang baik. Sekarang pompa semprot sudah cukup terisi untuk selama dua minggu. Jika pompa semprot tidak digunakan lebih dari dua minggu, pengisian kembali dilakukan dengan menyemprot satu kali. Posisi ujung semprotan menjauh dari anda pada saat melakukan hal tersebut diatas.

Cara Penggunaan

4. Jika perlu, hembuskan hidung untuk membersihkan lubang hidung.
5. Pegang pompa semprot KUAT-KUAT dengan telunjuk dan jari tengah pada kedua sisi ujung semprotan serta ibu jari pada bagian dasar botol. Letakkan jari telunjuk pada tepi pompa bagian atas
6. Letakkan ujung semprotan ke dalam salah satu lubang hidung (bagian ujung tidak boleh masuk terlalu jauh ke dalam hidung). Rendahkan kepala kea rah depan, hingga semprotan dapat mencapai bagian belakang hidung.

7. Arahkan bagian ujung lurus ke dalam hidung. Tutup lubang hidung yang lainnya dengan jari. Pompa alat semprot dengan menekan botol menggunakan ibu jari SECUKUPNYA dan CEPAT untuk penyemprotan yang penuh dan hiruplah pada saat yang sama, secara perlahan-lahan. Ulangi prosedur untuk lubang hidung lainnya.

8. Ulangi langkah 5, 6 dan 7 jika harus menggunakan lebih dari satu semprotan kedalam lubang hidung.
9. Hindari mengembuskan hidung selama 15 menit setelah pemberian dosis. Untuk hasil yang terbaik, obat ini harus digunakan secara teratur.

Setelah penggunaan

Bersihkan ujung semprotan secara hati-hati dengan kain atau tisu bersih, dan tutup kembali. Jika semprotan tidak bekerja dan mungkin mampat, bersihkan sesuai dengan petunjuk dibawah. Jangan pernah mencoba untuk membuka penghalang atau membesarkan lubang semprotan dengan peniti atau bahan tajam lainnya karena akan merusak cara kerja semprotan. Semprotan harus dibersihkan minimal sekali seminggu atau lebih sering jika mampat.

Cara membersihkan semprotan

1. Lepaskan tutup dan ujung semprotan (lihat gambar dibawah)

2. Rendam ujung semprotan dan tutup dalam air hangat selama beberapa menit, kemudian bilas dengan air kran yang dingin.

3. Hilangkan sisa air dengan mendiamkan hingga kering.
4. Pasang kembali ujung seprotan
5. Isi semprotan secukupnya sehingga terisi dengan baik dan gunakan sebagaimana biasanya
6. Pasanglah kembali penutup pada pompa semprot jika tidak digunakan.

Penyimpanan

Simpan pada suhu dibawah 30°C.
Pakai dalam waktu 2 bulan setelah penggunaan pertama dan kemudian, buang.
Sisa suspensi tidak boleh dipindahkan ke botol lain.
Jauhkan dari jangkauan anak-anak.

Batas kadaluarsa

Jangan pakai jika tanggal kadaluarsa pada botol dan dus sudah terlampaui.

Kemasan

Botol terbuat dari polietilen, dilengkapi dengan pompa semprot dosis-terukur.
Tiap botol NASACORT AQ mengandung 16,5 gram suspensi, dengan 9,075 mg triamsinolon asetonid, dan menghasilkan minimal 120 semprotan.

No.Reg: DKI 0188400756A1

HARUS DENGAN RESEP DOKTER

550368

SANOFI

Regional Packaging Unit (RPU)

GENERAL

Code	: 550368
Update	: 25/06/2020 - Ver 1
Local Code SCM	: N/A
Current Item Code	: 547057
Product/Item Type	: Nasacort AQ 55mcg Nassal Spray PIL
Pack Size	
Box of	: 00s
Blister	: 0 × 00
Country	: Indonesia
Languages	: English/Bahasa
Market Barcode	: N/A
Artwork By	: Edwin PEQUERO
Revised By	: E. AMIHAN / E. PEQUERO
Plant	: REC - SG

TECHNICAL

Format	: 148 × 210 mm
Plant Barcode	: N/A
Color/s	: 1
	Pantone Reflex Blue CVC
Font/s	: Ocean Sans Pro SAN: Light, Bold
Size	: 7 pt
Technical Plans	: N/A

DISETUJUI OLEH BPOM : 27/04/2021 ID : EREG100022VR12000248