SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
STERONASE AQ Nasal Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Triamcinolone acetonide 0.055%W/W.
Bottles of STERONASE AQ Nasal Spray contain 16.5 g of suspension (with 9.075 mg triamcinolone acetonide). One delivered dose contains 55 micrograms of triamcinolone acetonide.
Excipient with known effect: 15 micrograms of benzalkonium chloride/delivered dose.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Nasal spray, suspension.
It is an unscented, off-white, thixotropic suspension of microcrystalline triamcinolone acetonide in an aqueous medium.

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
STERONASE AQ Nasal Spray is indicated for the treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

4.2. Posology and method of administration
Posology

Adults and Adolescents 12 years of Age and older: The recommended starting and maximum dose is 220 micrograms as 2 sprays in each nostril once daily. Titrate 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.

Children 6 to 12 years of age: The recommended starting dose is 110 micrograms per day given as 1 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 are controlled, patients should be maintained on the lowest effective dose once daily [*see Warnings and Precautions (4.4and Pharmacodynamic Properties (51*].

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 Precautions4.4, and Pharmacodynamic Properties (51*)].

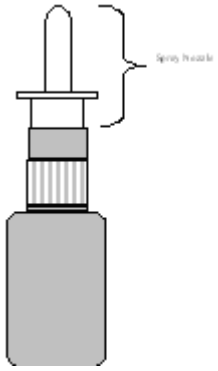
STERONASE AQ Nasal Spray is not recommended for children under 2 years of age.

Continuous use beyond 3 months in children under 12 years is not recommended.

4.2.1 Administration Information
Method of administration
STERONASE AQ Nasal Spray is for nasal use only.
It is important to shake the bottle gently before each use.
If adequate relief of symptoms has not been obtained after 3 weeks of treatment, STERONASE AQ Nasal Spray should be discontinued. 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. STERONASE AQ Nasal Spray will remain adequately primed for 2 weeks. If the product is unused for more than 2 weeks, then it can be

adequately reprimed with one spray. The nozzle should be pointed away from you while you are doing this.
After using the spray: Wipe the nozzle carefully with a clean tissue or handkerchief, and replace the cap.
If the spray does not work and it may be blocked, clean it as follows. NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.
The nasal spray should be cleaned at least once a week or more often if it gets blocked.

TO CLEAN THE SPRAY
1. Remove the cap and the spray nozzle only* (pull off).
2. Soak the cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.
3. Shake or tap off the excess water and allow to air-dry
4. Re-fit the spray nozzle.
5. Prime the unit as necessary until a fine mist is produced and use as normal.
* Part as indicated on diagram below,



Also, the bottle should be discarded after 120 actuations or within 2 months of starting treatment (16.5 g pack). Do not transfer any remaining suspension to another bottle.

4.3. Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use
If there is any reason to suppose that adrenal function is impaired, care must be taken while transferring patients from systemic steroid treatment to STERONASE AQ Nasal Spray.
In clinical studies with STERONASE AQ 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 temporary discontinuation of treatment with STERONASE AQ Nasal Spray.

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

STERONASE AQ Nasal Spray contains benzalkonium chloride, long term use may cause oedema of the nasal mucosa.

Paediatric population

STERONASE AQ Nasal Spary is not recommended for use in children under 2 years of age. Reduction in growth velocity has been reported in children receiving nasal corticosteroids, including STERONASE AQ Nasal Spray at licensed doses. See section 5.1.

It is recommended that the height of children receiving treatment with nasal corticosteroids is regularly monitored. Therapy should be managed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. 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.

4.5. 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.

4.6 Fertility, pregnancy and lactation

Clinical experience in pregnant women is limited. In animal studies, corticosteroids have been shown to induce teratogenic effects. Triamcinolone acetonide may pass into human breast milk. Triamcinolone acetonide should not be administered during pregnancy or lactation unless the therapeutic benefit to the mother is considered to outweigh the potential risk to the foetus/baby

4.7 Effects on ability to drive and use machines

STERONASE AQ Nasal Spray has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

The adverse events reported in clinical trials with STERONASE AQ Nasal Spray 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 2 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 (see also section 4.4).

Respiratory, thoracic and mediastinal disorders
Common: bronchitis, epistaxis, cough

Rare: nasal septum perforations
Not known: nasal irritation, dry mucous membrane, nasal congestion, sneezing, dyspnoea

• Gastrointestinal disorders
Common: dyspepsia, tooth disorder
Not known: nausea

• General disorders and administration site conditions
Not known: fatigue

• Investigations
Not known: decreased blood cortisol

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

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/ **4.9. Overdose**
Like any other nasally administered corticosteroid, acute overdosing with STERONASE AQ 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: 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
STERONASE AQ 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 STERONASE AQ Nasal Spray and relief may be expected in 3 to 4 days. When STERONASE AQ Nasal Spray 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, and in children 2 to 5 years of age at 110 μg/day intranasally, no suppression of the Hypothalamic-Pituitary-Adrenal (HPA) axis has been observed.

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

5.2 Pharmacokinetic properties
Single dose intranasal administration of 220 micrograms of STERONASE AQ Nasal Spray 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 STERONASE AQ Nasal Spray.
Paediatric population
Following multiple doses intranasal administration of STERONASE AQ, systemic exposures observed in paediatric patients 6 to 12 years of age were similar to those observed in adult patients. Intranasal administration of STERONASE AQ 110 μg once daily in pediatric patients 2 to 5 years of age exhibited similar systemic exposure to that achieved in adult patients at a dose of 220 μg once daily.
The apparent clearance and volume of distribution in pediatric patients 2 to 5 years of age were found to be approximately half of that in adults.

5.3 Preclinical safety data
In pre-clinical studies, only effects typical of glucocorticoids were observed.
Like other corticosteroids, triamcinolone acetonide (administered by inhalation or other routes) has been shown to be teratogenic in rats and rabbits, resulting in cleft palate and/or internal hydrocephaly and axial skeletal defects. Teratogenic effects, including CNS and cranial malformations, have also been observed in non-human primates.

No evidence of mutagenicity was detected in in-vitro gene mutation tests.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
-Glucose anhydrous, Microcrystalline cellulose and carboxymethylcellulose sodium, disodium edetate, benzalkonium chloride, polysorbate 80, purified water, Hydrochloric acid or sodium hydroxide (for adjustment of pH).

6.2 Incompatibilities
Not applicable

6.3 Shelf life
Unopened: The expiry date of the product is indicated on the packaging materials.
After first opening: 2 months.

6.4 Special precautions for storage: Do not store above 25°C. For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container
STERONASE AQ Nasal Spray is contained in a 20 mL high density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit. One Bottle of STERONASE AQ Nasal Spray contains 16.5 g of suspension, providing 120 actuations.

6.6 Special precautions for disposal
No special requirements

7. MARKETING AUTHORISATION HOLDER
Sanofi-Aventis Israel Ltd. POB 8090 Netanya Israel

8. MANUFACTURER
Aventis Pharma UK

Revised in February 2021 according to MOHs guidelines

STER-NASAL-16