

NASONIDE NASAL SPRAY

Triamcinolone Acetonide 55mcg/dose

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This leaflet answers some common questions about NASONIDE NASAL SPRAY. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking NASONIDE NASAL SPRAY against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What NASONIDE NASAL SPRAY is used for

NASONIDE NASAL SPRAY is used to treat an itchy or runny nose, sneezing or other symptoms caused by seasonal and perennial (present throughout the year) allergic rhinitis (an allergic inflammation of the nasal airways).

NASONIDE NASAL SPRAY is suitable for adults and children 2 years and over.

How NASONIDE NASAL SPRAY works

NASONIDE NASAL SPRAY contains the active ingredient triamcinolone acetonide.

Triamcinolone acetonide belongs to a group of medicines called corticosteroid (steroid for short) which has an anti-inflammatory action. The tiny amounts sprayed into your nose help to reduce swelling and irritation.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use NASONIDE NASAL SPRAY

-When you must not use it

Do not use NASONIDE NASAL SPRAY:

- If you have an allergy or have had an adverse reaction to any of this medicine related ingredients.
- After the expiry date printed on the pack.
- If the packaging is torn or shows signs of tampering.

-Before you start to use it

Tell your pharmacist or doctor:

- Your medical conditions or allergies you may have, and any significant facts about your health.

Growth retardation has been reported in children receiving nasal corticosteroid. It is recommended to monitor the height of children receiving prolonged treatment with this medication.

Pregnancy and breast feeding:

- NASONIDE NASAL SPRAY should not be administered during pregnancy or lactation unless the therapeutic benefit to the mother is considered to outweigh the potential risk to the baby.
- Triamcinolone acetonide may pass into human breast milk. Ask your doctor or pharmacist

for advice before taking this medicine if you are pregnant, planning to become pregnant or breast-feeding.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use NASONIDE NASAL SPRAY

-How much to use

If NASONIDE NASAL SPRAY has been prescribed for you by your doctor, follow the instructions he/she may have given you.

Aged 12 years and over:

The recommended starting dose is 220µg once daily (2 sprays in each nostril). Once symptoms are controlled, the dose can be maintained at 110 µg once daily (1 spray in each nostril)

Children aged 6 to 12 years:

The recommended dose is 110 µg once daily (1 spray in each nostril). In more severe symptoms, a dose of 220µg once daily (2 sprays in each nostril) may be used. But once the symptoms are controlled, the dose should be maintained at the lowest effective dose.

Children aged 2 to 5 years:

The recommended and maximum dose is 110 µg once daily (1 spray in each nostril).

NASONIDE NASAL SPRAY is not recommended for children under 2 years of age.

How to use the spray:

- a) Blow the nose gently to clear nostrils.
- b) Shake the bottle gently.
- c) For first time use, hold the bottle upright and fill the pump by pressing the nozzle downwards and releasing it 5 times, until a fine spray is produced.

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- d) Closed one nostril with finger. Hold the bottle upright and insert the nozzle into the nostril as far as is comfortable. Whilst breathing in gently through the nose with the mouth closed, press the bottle upwards once to deliver one spray.
- e) Breathe out through the mouth.
- f) Repeat step d) and e) for the other nostril.
- g) For children aged 12 years and older, step d), e) and f) should be repeated once more to achieve the recommended dosage of 2 sprays into each nostril.
- h) Wipe the spray nozzle with clean tissue after each use to keep it clean and replace the cap.

If the nasal spray has not been used for 2 weeks or more, it needs to be sprayed once into the air before use. The nozzle should be pointed away while doing this. Always shake the bottle gently before use.

Never try to unblock or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism. If the spray does not work and it may be blocked, clean it as follows;

How to clean the spray:

- a) Remove the cap and pull off the spray nozzle only.
- b) Soak the dust-cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.
- c) Shake or tap off the excess water and allow to air-dry.
- d) Re-fit the spray nozzle.
- e) Prime the unit as necessary until a fine mist is produced and use as normal.

The nasal spray should be cleaned at least once a week or more often if it gets blocked.

-When to use it

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from

the information contained in this leaflet.

-How long to use it

An improvement 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 symptoms are stabilized.

If adequate relief of symptoms has not been obtained after 3 weeks of treatment, NASONIDE NASAL SPRAY should be discontinued.

If you are not sure how long you should be using NASONIDE NASAL SPRAY, check with your doctor. If your condition does not improve after the treatment course, or if it becomes worse, contact your doctor.

-If you forget to use it

It is important to use this medication exactly as prescribed by your doctor. If you forget to apply this medication, apply it as soon as you remember. If it is almost time for your next application, skip the missed dose and continue with your regular schedule. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

No information is available concerning overdosage in human beings following nasally administered corticosteroid. Some may experience gastrointestinal upset if taken orally.

If you suspect that you are overdosed, please consult your pharmacist or doctor. Bring any remaining medicine with you.

While you are using NASONIDE NASAL SPRAY

-Things you must do

Blow the nose gently to clear nostrils. Shake the bottle gently. If you are about to start taking on any other new medicine, tell your

pharmacist or doctor that you are taking NASONIDE NASAL SPRAY.

-Things you must not do

Do not continue NASONIDE NASAL SPRAY if you have irritation or sensitization after using this medicine.

Do not give this medication to anyone else, even if they have the same symptoms as you do. It can be harmful for people to use this medication if their doctor has not prescribed it.

-Things to be careful of

Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, NASONIDE NASAL SPRAY should be used with caution until healing has occurred.

This medication is for nasal use only. Should not be used in or near eye area. If this occurs, bathe your eye with eyewash if possible. Your eye may sting. If you start having any problem with your sight or your eye is sore, contact your doctor immediately.

Do not swallow this medication. Small quantity may not cause any harm. If you accidentally swallow in a larger quantity, please contact your doctor immediately.

Side effects

Like other medicines, NASONIDE NASAL SPRAY can cause some side effects. Some may be serious and need medical attention.

The most commonly reported adverse effects are;

- Rhinitis (irritation and inflammation of the mucous membrane inside the nose)
- Headache
- Pharyngitis (inflammation of the pharynx, a region in the back of the throat)

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Respiratory disorders:

- Epistaxes (nosebleeds)
- Nasal irritation
- Dry mucous membrane
- Naso-sinus congestion (stuffy nose) and sneezing
- Nasal septal perforations (nasal septum, the cartilaginous membrane dividing the nostrils, develops a hole or fissure) (rarely)

Skin or subcutaneous disorders; rarely allergic reactions including:

- Rash
- Urticaria (itchy areas of skin that are usually a sign of an allergic reaction)
- Pruritus (severe itching of the skin)
- Facial oedema (swelling of the face)

Systemic effects (affecting the whole body) of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of NASONIDE NASAL SPRAY

-Storage

Store below 30°C.
Keep bottle in upright position.
Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date. Medicines should not be disposed of via wastewater or household waste, Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

NASONIDE NASAL SPRAY is an opaque off-white slight viscous suspension.

NASONIDE NASAL SPRAY available in 15ml plastic metered spray bottle.

-Ingredients

-Active ingredient:

Each bottle contains 55mcg/dose of Triamcinolone acetonide.

-Inactive ingredients:

Benzalkonium Chloride, Microcrystalline Cellulose, Carboxymethyl Cellulose Sodium, Disodium Edetate, Hydrochloric Acid, Dextrose Anhydrous, Polysorbate 80, Purified Water.

-MAL number:

MAL11055001A

Manufacturer

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42000 Port Klang, Selangor,
Malaysia.

Product Registration Holder:

HOE Pharmaceuticals Sdn. Bhd.
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Date of revision

-16/03/2015

Serial number

BPFK (R4/1)160315/00042