**PATIENT INFORMATION LEAFLET**

**Read all of this leaflet carefully before you start using AEROMIDE NASAL 100.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AEROMIDE NASAL 100** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**SCHEDULING STATUS**

S2

**PROPRIETARY NAME (and dosage form)**

**AEROMIDE NASAL 100**

aqueous nasal spray

## 1. WHAT AEROMIDE NASAL 100 CONTAINS

The active substance is budesonide. Each metered dose contains 100 μg budesonide. The other ingredients are glucose anhydrous, sodium carboxymethylcellulose/ microcrystalline cellulose, polysorbate 80, disodium edetate, hydrochloric acid, purified water and potassium sorbate as preservative.

## 2. WHAT AEROMIDE NASAL 100 IS USED FOR

**AEROMIDE NASAL 100** is used to prevent inflammation of the mucous membranes of the nose caused by allergies to pollen or grass (seasonal hay fever) thus relieving nasal congestion (blocked nose), runny nose, sneezing and nasal itching.

## 3. BEFORE YOU USE AEROMIDE NASAL 100

Do not use **AEROMIDE NASAL 100:**

- If you are allergic to budesonide or any of the ingredients listed in Section 1 ('**WHAT AEROMIDE NASAL 100 CONTAINS'**).
- If you have TB (tuberculosis).
- If you have any infection in your nasal passage or sinuses.
- In children under the age of 12 years.

**Take special care with AEROMIDE NASAL 100**

- If you use **AEROMIDE NASAL 100** every day for a long time, your doctor will need to regularly check the inside of your nose (the nasal mucosa).

- The full effect of **AEROMIDE NASAL 100** is not achieved until after a few days, therefore for this treatment to work effectively you must use it regularly, even if your symptoms are under control or you have no symptoms at all.
- If you get a chest infection, chickenpox, measles or other infection, see your doctor immediately.
- If you have been taking high doses of inhaled steroids for a long time you may need to take steroid tablets during periods of stress. Please tell your doctor that you are using **AEROMIDE NASAL 100** if you get a severe infection, have a severe asthma attack, have an accident, have to go to hospital or have an operation.
- Tell your doctor if you have liver problems.
- Children over the age of 12 taking this medicine for a long time need to have their growth/height checked regularly by their doctor.
- Tell your doctor if you have been diagnosed with diabetes (high blood sugar), low bone mineral density (osteoporosis) or ulcers in the stomach or first part of the small intestine (peptic ulcer).
- Tell your doctor if you experience a change in your vision, have increased pressure in your eye (glaucoma) or eye problems such as clouding of the lens (cataracts).
- If you have recently had an ulcer of the nasal septum (membrane separating the nostrils), nasal surgery or nasal injury you should not use **AEROMIDE NASAL 100** until your nose has healed.
- **AEROMIDE NASAL 100** contains 9,5 mg of glucose per daily maximum recommended daily dose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor BEFORE taking this medicine.

**Pregnancy and Breastfeeding**

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

**Driving and using machinery**

Do not drive or operate any tools or machinery if you suffer from any side effects such as dizziness during treatment with **AEROMIDE NASAL 100**, which may affect your ability to do these activities safely.

**Using other medicines with AEROMIDE NASAL 100**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor, pharmacist or healthcare provider if you are taking any of the following medicines as they may affect your treatment with **AEROMIDE NASAL 100**, or your treatment with these medicines may be affected by **AEROMIDE NASAL 100**

- Other cortisone-containing products taken by mouth or injection

- Ketoconazole and itraconazole (antifungal medicines)
- Clotrimazole, troleoandromycin and clarithromycin (anti-infective/antibiotic medicines)
- Ritonavir and indinavir (antiviral medicines)
- Cyclosporine (a medicine often used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome)
- Ethinylestradiol (hormone treatment)
- Cimetidine (used to reduce stomach acidity and treat ulcers)
- Diltiazem (used to treat angina and high blood pressure)
- Carbamazepine, phenytoin and phenobarbitone (usually used to prevent epileptic fits)
- Rifampicin (used for treatment of tuberculosis)

## 4. HOW TO USE AEROMIDE NASAL 100

Always take **AEROMIDE NASAL 100** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The initial dose of **AEROMIDE NASAL 100** for adults and children 12 years of age and older is two sprays (100 μg per spray) into each nostril in the morning or one spray into each nostril in the morning and evening. The maximum dose per day should not be more than 400 μg. Your doctor or pharmacist may reduce your dose of **AEROMIDE NASAL 100** at a later stage, to a lower dose that adequately controls your symptoms.

The full effect of **AEROMIDE NASAL 100** is not achieved until after a few days and full therapeutic benefit requires regular use of **AEROMIDE NASAL 100**.

If you get the impression that the effect of **AEROMIDE NASAL 100** is too strong or too weak for you, tell your doctor or pharmacist.

To obtain the best results from your **AEROMIDE NASAL 100** aqueous nasal spray, follow the instructions given below. If you are still unclear about how to use the device, ask your doctor or pharmacist to explain.

**General instructions on how to use your nasal spray**

1. **Shake the bottle vigorously 3 to 4 times.**
2. Remove the protective cap from the nasal applicator.
3. When using the spray for the first time, you must load the pump by pressing downward on the collar. To do this, hold the bottle upright, place your index and middle finger either side of the bottleneck on the collar provided, while supporting the base of the bottle with your thumb (see **Fig. 1**). Press down 5 to 10 times until a fine spray appears. The nasal spray is now ready for use. If you do not use **AEROMIDE NASAL 100** daily, the pump will need to be loaded with medicine again. This time it will be sufficient to spray just once into the air.
4. Gently blow your nose.
5. Hold the bottle as shown in **Fig. 1**



Fig 1.

6. Tilt your head forward slightly, close one nostril with a finger and gently insert the tip of the nasal applicator into the other nostril. (See **Fig. 2**)

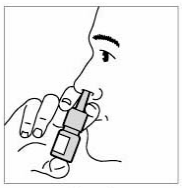


Fig 2.

7. For each spray your doctor or pharmacist has instructed you to take, press firmly downwards once on the collar.
8. Inhale gently through the nostril, then gently breathe out through the mouth.
9. Repeat the procedure with the other nostril.
10. Replace the protective cap on the nasal applicator after use.

**Cleaning**

Clean the upper plastic parts at least once a week or at any time the medicine is not coming out as it should. Remove the protective cap and lift off the nasal actuator. Wash the plastic parts in warm water. Allow the plastic parts to air dry completely before replacing them. The actuator should not be unblocked with a pin or other sharp object. After cleaning, the pump will need to be loaded with medicine again, before use.

**If you use more AEROMIDE NASAL 100 than you should**

If you inhale too many intranasal sprays of **AEROMIDE NASAL 100** consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to use AEROMIDE NASAL 100**

Inhale an intranasal dose when you remember *but* if it is near to the time for the next dose, wait until this is due. Do not take a double dose to make up for forgotten individual doses. Then carry on as before.

## 5. POSSIBLE SIDE EFFECTS

**AEROMIDE NASAL 100** can have side effects.

The following side effects occur frequently:

- Mild and transient burning, dryness or other irritation inside the nose
- Voice disorders

The following side effects occur less frequently:

- Fungal infections of the nose or mouth/throat
- Dizziness or light-headedness
- Increased pressure in the eye (glaucoma) or clouding of the lens (cataract)
- Crusting inside the nose, bloody mucus or unexplained nosebleeds (especially if the spray is improperly aimed towards the nasal septum), runny nose, stuffy nose, sneezing, sores inside the nose, throat irritation, sore mouth and/or throat, dry throat, cough, perforated nasal septum
- Diarrhoea, nausea or vomiting, changed sense of taste
- Skin rash, hives, itching
- Depression, irritability, anxiety, feeling aggressive
- Muscle or joint pain
- Weakness, tiredness

The following side effects may occur but their frequency is not known:

- Swelling of your skin, eyes, lips and face or swelling or tingling in your mouth or throat, feeling faint, chest pain or tightness and trouble breathing. If any of the above occurs, you may be having an allergic reaction and should see your doctor immediately.
- Headache
- Unusual behavior (in children over the age of 12), nervousness, restlessness
- A slowing of the rate of growth of children over the age of 12, decrease in bone density
- Thirst

Not all side effects reported for **AEROMIDE NASAL 100** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **AEROMIDE NASAL 100**, please consult your doctor, pharmacist or other healthcare professional for advice.

## 6. STORING AND DISPOSING OF AEROMIDE NASAL 100

Store **AEROMIDE NASAL 100** aqueous nasal spray at or below 25 °C.

STORE THIS MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label bottle or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7. PRESENTATION OF AEROMIDE NASAL 100

Amber glass bottle containing 10 ml of suspension (200 doses) fitted with a pump spray, nasal actuator and protective cap. The bottle is packed in an outer carton.

## 8. IDENTIFICATION OF AEROMIDE NASAL 100

A white opalescent viscous suspension, which requires vigorous shaking before use.

## 9. REGISTRATION NUMBER

41/21.5.1/0238

## 10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Activo Health (Pty) Ltd.
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Arena Office Park
272 West Avenue
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## 11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Registration date: December 2008
Publication date: 25 January 2022

NS1 Namibia Reg. No.: 10/21.5.1/0118