PATIENT INFORMATION LEAFLET FOR AEROMIDE INHALER

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

AEROMIDE inhaler

Read all of this leaflet carefully before you start using

AEROMIDE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AEROMIDE** 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.

1. WHAT AEROMIDE CONTAINS

Each inhalation delivers:

Budesonide	200 µg
Ethanol	1 % *w/w*

The other ingredients are propellant 1,1,1,2-tetrafluoroethane, sorbitan trioleate.

2. WHAT AEROMIDE IS USED FOR

AEROMIDE is used to treat and prevent symptoms of asthma.

It belongs to a group of medicines called corticosteroids.

3. BEFORE YOU USE AEROMIDE

Do not use AEROMIDE:

- If you are hypersensitive (allergic) to budesonide or any of the other ingredients of **AEROMIDE** (see **WHAT AEROMIDE CONTAINS**).
- If you have pulmonary tuberculosis (TB).
- If you have any untreated bacterial, viral or fungal infections in your mouth, airways or lungs.
- If you are pregnant or breastfeeding your baby (See **Pregnancy and breastfeeding**).

Take special care with AEROMIDE:

- Always use **AEROMIDE** according to the instructions, this will ensure that **AEROMIDE** reaches the areas of your lungs that it should (see **HOW TO TAKE AEROMIDE**).
- Use **AEROMIDE** regularly even if you don't have any symptoms.
- Rinse your mouth after inhaling your dose in order to avoid a fungal infection in your mouth.
- If you are taking other corticosteroid medicines by mouth. **AEROMIDE** will be given to you in combination with the previously used oral steroid dose for about ten days. After this period, a reduction of the oral corticosteroid will be started.
- You may experience uneasiness during the withdrawal period due to decreased steroid effect, which may result in the appearance of allergic or inflammatory symptoms such as swelling and irritation inside the nose, irritated and red skin, and muscle and joint pain.
- During the withdrawal of oral steroids, you may feel unwell in a non-specific way. You should continue using **AEROMIDE** whilst withdrawing the oral steroid. You may experience symptoms such as tiredness, headache, nausea and vomiting. In these cases, a temporary increase in the dose of oral corticosteroids might be necessary.
- You might also experience constriction of the airways (tightening of the chest) with an increase in wheezing after using **AEROMIDE**. If this occurs, treatment with **AEROMIDE** should be stopped immediately. Your doctor will assess you and suggest an alternative therapy.
- You should not use **AEROMIDE** for fast relief of sudden episodes of asthma where an

inhaled short-acting bronchodilator (a medicine used to open up the airways to your lungs) is required. If you find that the short-acting bronchodilator treatment is not working or if you need more inhalations than usual, you should seek medical attention.

- Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. This may cause changes in bone mineral density (thinning of the bones), a slowing of the rate of growth of children and adolescents and an effect on the adrenal gland (a small gland next to the kidney).
- If you have a history of increased pressure in your eyes or an eye disorder called glaucoma
- If you have to go for surgery or emergency treatment, always tell your doctor that you are using **AEROMIDE**
- If you have a lung disease known as Chronic Obstructive Pulmonary Disease (COPD) you are at risk of developing pneumonia, if you smoke, are of older age or have a low body mass index (BMI). Symptoms of pneumonia include coughing, fever, sweating, shaking chills, rapid/shallow breathing, shortness of breath, loss of appetite, low energy or fatigue.
- If you have a cold or chest infection or any problems with your breathing.
- If you have liver problems.
- If you are using long-term medicines to treat fungal or viral infections (such as itraconazole, ketoconazole and HIV protease inhibitors) since these medicines may increase the risk of experiencing side effects.

Pregnancy and breastfeeding:

Do not use **AEROMIDE** if you are pregnant or breastfeeding your baby (See **Do not use AEROMIDE)**.

If you get pregnant while using **AEROMIDE**, do not stop using **AEROMIDE,** but consult your healthcare provider immediately. It is important for both the baby and mother to maintain suitable asthma treatment during pregnancy.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for

advice before using **AEROMIDE**.

Driving and using machinery:

AEROMIDE is not likely to affect you being able to drive or use any machines.

Taking other medicines with AEROMIDE:

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

Tell your doctor if you are taking any of the following:

- itraconazole and ketoconazole (antifungal medicine)
- HIV protease inhibitors (antiviral medicines)
- oestrogens and contraceptive steroids

4. HOW TO USE AEROMIDE

Do not share medicines prescribed for you with any other person.

Always use **AEROMIDE** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Shake before use.

Rinse your mouth after each dose.

Adults and children over 12 years:

The usual dose is 200 µg (1 puff) twice daily.

Your total daily dosage may be increased up to 1 600 µg (8 puffs), if your asthma is not responding to low dose therapy.

Your doctor will tell you how long your treatment with **AEROMIDE** will last. Do not stop your treatment with **AEROMIDE** suddenly.

If you are using a bronchodilator inhaler with **AEROMIDE**, use the bronchodilator inhaler first and wait several minutes before using your **AEROMIDE** inhaler to minimise possible local side effects, such as cough.

If your daily dose exceeds 400 µg (2 puffs), you should use a spacer device when inhaling **AEROMIDE**. Children need to use a spacer irrespective of the dose.

How to use your inhaler correctly:

Follow the instructions carefully.

1. Before using the **AEROMIDE** inhaler for the first time or if it has not been used for a week or more, release one puff into the air.
2. Remove the mouthpiece cover and check the mouthpiece thoroughly to see that it is clean.
3. Shake vigorously.
4. Hold the inhaler between your index finger and thumb.
5. Breathe out gently through your mouth and immediately place the mouthpiece in the mouth between your teeth (do not bite it).
6. Grip the mouthpiece firmly with your lips.
7. Tilt your head slightly backwards.
8. Start breathing in slowly through your mouth. At the same time press the canister down, to release the one dose while continuing to breathe in steadily and deeply.
9. Remove the inhaler from your mouth.
10. Hold your breath for at least 10 seconds or for as long as it is comfortable.
11. Breathe out slowly.
12. If another dose is required, wait for at least one minute and repeat the steps.
13. After use, replace the mouthpiece cover.

Do not rush steps 4 – 8. It is important to breathe in slowly through your mouth just before pressing the canister. To be sure of using your inhaler properly, you may initially practise these steps in front of a mirror.

Children:

Your child may need your help. To help your child, you must first learn the technique correctly, then properly guide your child to use the inhaler.

Cleansing:

1. Clean your inhaler at least once a week.
2. Gently pull the metal canister out of the adaptor of the inhaler.
3. Remove the mouthpiece cover.
4. Rinse the adaptor and the mouthpiece cover in warm water, but do not put the metal canister into the water.
5. Leave to dry in a warm place. Avoid excessive heat.
6. Replace the canister and the mouthpiece cover correctly.

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

If you use more AEROMIDE than you should:

It is important that you take your dose as advised by your doctor or healthcare provider. In the event of an overdosage, consult your doctor or pharmacist for advice. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use AEROMIDE:

Use your **AEROMIDE** inhaler as soon as you remember. If it is almost time for your next usual dose, skip the missed dose and continue using your **AEROMIDE** inhaler at your regular time. Do not use a double dose of **AEROMIDE** to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

AEROMIDE can have side effects

Not all side effects reported for **AEROMIDE** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **AEROMIDE**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **AEROMIDE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- rash, hives or itching.
- sudden wheezing after inhaling **AEROMIDE**.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AEROMIDE**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Thrush (a fungal infection in the mouth), pneumonia (infection of the lung) in COPD patients.
- Feeling nervous, restless, depressed.
- Psychosis (loss of contact with reality, impaired thoughts and emotions).
- Difficulty in speaking due to a physical disorder of the mouth, tongue, throat or vocal cords (dysphonia).
- Cold-like symptoms, throat irritation, cough, hoarseness.
- Dry mouth and throat, bad taste in your mouth.
- Unusual bleeding or bruising under the skin, thinning of your skin.

Less frequent side effects:

- Feeling worried-anxious, sleeping problems, feeling over excited or irritable aggressiveness, behavioural changes

- Headache, trembling and shaking
- Blurred vision
- Constriction of air passages, difficulty breathing, wheezing
- Nausea (feeling sick), diarrhoea
- Bruising of the skin
- Muscle cramps
- Thirst, tiredness
- Inability of the adrenal glands to function normally, affecting hormone production and slowing of the rate of growth of children and adolescents.

Side effects of unknown frequency:

- Increased pressure in the eye (glaucoma).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF AEROMIDE

Store at or below 30 °C.

Do not freeze.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF AEROMIDE

One inhaler with leaflet to be packed in a cardboard carton. Each canister provides 300 metered doses.

8. IDENTIFICATION OF AEROMIDE

A suspension of budesonide, filled in a plain aluminium aerosol can with silver ferrule valve provided with a PP actuator with a maroon body and grey cap.

9. REGISTRATION NUMBER

50/21.5.1/0261

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

Forrester Pharma (Pty) Ltd

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