PROFESSIONAL INFORMATION FOR AEROMIDE

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

AEROMIDE inhaler.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each actuation delivers 200 µg budesonide.

Each actuation delivers ethanol, 1 % *w/w*.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Metered dose inhaler

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AEROMIDE is indicated for the prophylaxis of the symptoms of asthma.

4.2 Posology and method of administration

Shake before use.

Adults and children over 12 years of age:

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Initial dose: 400 µg daily in divided doses.

In patients whose asthma is not responding to low dose AEROMIDE therapy, or when the patient's asthma can no longer be controlled by the maximum maintenance dose of bronchodilators, the daily dosage may be increased up to 1 600 µg. In controlled patients, twice daily administration may be adequate.

THE MAINTENANCE DOSE SHOULD BE INDIVIDUALISED AND SHOULD BE THE LOWEST POSSIBLE DOSAGE.

Patients on concomitant therapy with inhaled bronchodilators should use the bronchodilators several minutes before the inhalation of AEROMIDE to minimise possible local side effects, such as cough. The use of a spacer device is recommended when the daily dose exceeds 400 µg in adults and for all doses in children. This will improve lung deposition and will reduce the systemic absorption of budesonide.

Rinse the mouth after each dosage administration.

Treatment with inhaled steroids should not be stopped abruptly.

How to use the inhaler correctly:

Follow the instructions carefully.

1. Before using the AEROMIDE inhaler for the first time or if it has not been 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 AEROMIDE inhaler between the index finger and the thumb.

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5. Breathe out fully through the mouth and immediately place the mouthpiece in the mouth between the teeth (do not bite it).
6. Grip the mouthpiece firmly with the lips.
7. Tilt the head slightly backwards.
8. Start breathing in slowly through the mouth. At the same time press the canister down to release one dose while continuing to breathe in steadily and deeply.
9. Remove the AEROMIDE inhaler from the mouth.
10. Hold the 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 the mouth just before pressing the canister. To be sure of using the AEROMIDE inhaler properly, practise these steps initially in front of a mirror.

Children:

Young children may need help. To help the child, parents must first learn the technique correctly themselves, then properly guide the child to use the AEROMIDE inhaler.

Cleansing:

1. Clean the AEROMIDE inhaler at least once a week.
2. Gently pull the metal canister out of the adaptor of the inhaler.
3. Remove the mouthpiece cover.

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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.

4.3 Contraindications

AEROMIDE is contraindicated in:

- Patients with hypersensitivity to budesonide or to any of the components of AEROMIDE listed in section 6.1.
- Patients with active or quiescent pulmonary tuberculosis (TB) or with other untreated airway infections of bacterial, fungal or viral origin.
- Pregnancy and lactation unless no safe/safer medicine is available, has failed, cannot be tolerated or contraindicated and treatment cannot be avoided. Use the lowest possible efficient dose and if possible, avoid in first trimester of pregnancy. Patients should be counselled of the possibility of teratogenicity.

4.4 Special warnings and precautions for use

Patients should be instructed in the correct method to use the AEROMIDE inhaler to ensure that the inhaler activation is synchronised with inspiration (see section 4.2).

Prophylactic treatment:

Patients should also be made aware of the prophylactic nature of AEROMIDE therapy and that it should be taken even when they are asymptomatic.

Candidiasis:

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The development of pharyngeal and laryngeal candidiasis may occur. Patients with high blood levels of *Candida* precipitants, indicating a previous infections, are most likely to develop this complication. Rinsing the mouth with water after each dose is recommended. The water should not be swallowed.

Systemic corticosteroid therapy:

The transfer of a patient dependent on oral steroids treatment to treatment with AEROMIDE demands special care and is preferably done when the patient is in a relatively stable phase. AEROMIDE should be given in combination with the previously used oral steroid dose for about ten days. After this period, the reduction of the oral corticosteroid can be started with a dose reduction corresponding to about 1 mg prednisolone per day per week. Some patients may experience uneasiness during the withdrawal period due to decreased steroid effect, which may result in the appearance of allergic or arthritic symptoms such as rhinitis, eczema and muscle and joint pain. Specific treatment should be initiated for these conditions. During the withdrawal of oral steroids, patients may feel unwell in a non-specific way, even though respiratory function is maintained or improved. Patients should be encouraged to continue with AEROMIDE therapy whilst withdrawing the oral steroid, unless there are clinical signs to indicate the contrary. A general insufficient glucocorticosteroid effect should be suspected if symptoms such as tiredness, headache, nausea and vomiting should occur. In these cases a temporary increase in the dose of oral glucocorticosteroids is sometimes necessary.

Paradoxical bronchospasm may occur, with an immediate increase in wheezing after dosing. If this occurs, treatment with inhaled budesonide, as in AEROMIDE, should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

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Patients who have previously been dependent on oral steroids may, as a result of prolonged systemic steroid therapy, experience the effects of impaired adrenal function. Recovery may take a considerable amount of time after cessation of oral steroid therapy, hence oral steroid-dependent patients transferred to budesonide, as in AEROMIDE, may remain at risk from impaired adrenal function for some considerable time. In such circumstances, HPA axis functions should be monitored regularly. Acute exacerbation, accompanied by increased mucous viscosity and mucous plugging may require complementary treatment with an oral corticosteroid and/or an antibiotic, if there is an infection.

It is important to monitor intercurrent infections and treat them appropriately.
The patient should be advised to use a short-acting inhaled bronchodilator as rescue medication to relieve acute asthma symptoms.

AEROMIDE is not intended for rapid relief of acute episodes of asthma where an inhaled short-acting bronchodilator is required.
If patients find short-acting bronchodilator treatment ineffective or they need more inhalations than usual, medical attention must be sought. In this situation consideration should be given to the need for or an increase in their regular therapy, e.g. higher doses of AEROMIDE or the addition of a long-acting beta agonist, or for a course of oral glucocorticosteroid.

Adrenal suppression may occur.
Appropriate measures should be taken to protect the patient against stress situations, e.g. severe infections, surgery. Treatment with AEROMIDE should not be stopped abruptly. Some patients may experience uneasiness during the

withdrawal period due to a decreased steroid effect. The healthcare professional may have to explain the reason for AEROMIDE treatment in order to encourage the patient to continue. The length of time needed for the body to regain its natural production of corticosteroids in sufficient amounts is often extensive. Thus, during physically stressing situations such as severe infections, trauma and surgical operations, it will be necessary to give the patient an additional oral steroid dose. Acute exacerbations, accompanied by increased mucous, viscosity and mucous plugging may require complementary treatments with an oral corticosteroid.

Systemic effects may occur with any inhaled corticosteroids, such as AEROMIDE, particularly at high doses prescribed for long periods. These effects are much less likely to occur with inhalation treatment than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important, therefore, that the dose of AEROMIDE is titrated to the lowest dose at which effective control of asthma is maintained.

Hepatic impairment:

Reduced liver function affects the elimination of corticosteroids causing lower elimination rate and higher systemic exposure. Be aware of possible systemic side effects.

CYP3A inhibitors:

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Co-treatment with CYP3A inhibitors, e.g. itraconazole, ketoconazole and HIV protease inhibitors are expected to increase the risk of systemic corticosteroid side effects. Therefore, the combination should be avoided. This is of limited importance for short-term (1-2 weeks) treatment with itraconazole or ketoconazole or other potent CYP3A inhibitors, but should be taken into consideration during long-term treatment. A reduction in the dose of AEROMIDE should also be considered (see section 4.5).

Pneumonia in patients with COPD:

An increase in pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids, including AEROMIDE. Healthcare professionals should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. Risk factors for pneumonia in patients with COPD include current smoking, older age, low body mass index (BMI) and severe COPD.

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.

Ethanol:

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per

actuation.

Paediatric population:

Influence on growth:

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids, like AEROMIDE, is regularly monitored. If growth is slowed, therapy should be re-evaluated with the aim of reducing the dose of AEROMIDE, if possible, to the lowest dose at which effective control of asthma is maintained. The benefit of the corticosteroid therapy and the possible risk of growth suppression must be carefully weighed. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.

4.5 Interaction with other medicines and other forms of interaction

The metabolism of AEROMIDE is primarily mediated by CYP3A4. Co-treatment with CYP3A inhibitors, e.g. itraconazole, ketoconazole and HIV protease inhibitors, are expected to increase the risk of systemic side effects (see section 4.4).
The combination of AEROMIDE with potent CYP3A inhibitors should be avoided 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. If AEROMIDE is co-administered with antifungals (such as itraconazole and ketoconazole), the period between treatments should be as long as possible. A reduction of the AEROMIDE dose could be considered.

Raised plasma concentrations of and enhanced effects of corticosteroids have been observed in women also treated with oestrogens and contraceptive steroids, but no effect has been observed with AEROMIDE and concomitant intake of low dose combination oral contraceptives.

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Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values).

Paediatric population:

Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

The safety of AEROMIDE in pregnancy and lactation has not been established.

Pregnancy

AEROMIDE is contraindicated in pregnancy. In animal reproduction studies, glucocorticosteroids have been shown to induce malformations (cleft palate, skeletal malformations).

Therapy with AEROMIDE should be regularly reviewed and maintained at the lowest lowest effective dose. It is important for both foetus and mother to maintain an adequate asthma treatment during pregnancy.

Breastfeeding

AEROMIDE is contraindicated in breastfeeding.

AEROMIDE is excreted in breast milk. Mothers using AEROMIDE should not breastfeed their babies.

4.7 Effects on ability to drive and use machines:

AEROMIDE has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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Tabulated list of adverse drug reactions

System Organ Class	Frequency	Adverse drug reaction
Infections and infestations	Frequent	Oropharyngeal candidiasis, pneumonia (in COPD patients).
Immune system disorders	Less frequent	Immediate and delayed hypersensitivity reactions (including rash, contact dermatitis, urticaria, angioedema and anaphylactic reaction)
Endocrine disorders	Less frequent	Signs and symptoms of systemic corticosteroid effects, including adrenal suppression and growth retardation
Psychiatric disorders	Frequent Less frequent	Psychotic behaviour nervousness, restlessness, depression Anxiety, psychomotor hyperactivity, sleep disorders, aggression, behavioural changes (predominantly in children)
Nervous system disorders	Less frequent	Headache, tremor
Eye disorders	Less frequent Frequency unknown	Cataract formation after prolonged use, vision blurred Glaucoma
Respiratory,	Frequent	Local/throat irritation and

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thoracic and mediastinal disorders	Less frequent	paradoxical bronchoconstriction, pulmonary infiltrates with eosinophilia, cough, hoarseness, dysphonia Bronchospasm
Gastrointestinal disorders	Frequent Less frequent	Dry mouth and throat, bad taste in the mouth Nausea, diarrhoea
Skin and subcutaneous tissue disorders	Frequent Less frequent	Skin thinning, purpura, urticaria, rashes, dermatitis Bruising
Musculoskeletal, connective tissue and bone disorders	Less frequent	Muscle spasm
General disorders and administration site conditions	Less frequent	Tiredness, thirst

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care professionals are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Symptoms:

Acute overdosage with AEROMIDE, even in excessive doses, is not expected to be

a clinical problem. The only harmful effect that follows inhalation of large amounts of AEROMIDE over a short period is suppression of hypothalamic pituitary-adrenal (HPA) function.

Treatment:

Treatment with AEROMIDE should be continued at the recommended dose to control the asthma and the appropriate measures taken to protect the patient against stress situations. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A 21.5.1 Corticosteroids and analogues

Mechanism of action

Budesonide is a non-halogenated corticosteroid, which, when inhaled, has a local anti-inflammatory action in the lungs. Budesonide is rapidly inactivated by the liver.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propellant 1,1,1,2-tetrafluoroethane,

sorbitan trioleate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

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6.4 Special precautions for storage

Store at or below 25 °C.

Do not freeze.

6.5 Nature and contents of container

Plain aluminium aerosol can with silver ferrule valve provided with a PP actuator with a maroon body and grey cap.

One inhaler with leaflet to be packed in a cardboard carton.

Each canister provides 300 metered doses.

6.6 Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Forrester Pharma (Pty) Ltd

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8. REGISTRATION NUMBER

50/21.5.1/0261

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 05 February 2020

10. DATE OF REVISION OF THE TEXT

15 September 2025