PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BUDAIR 0,25 mg/ml

BUDAIR 0,5 mg/ml

(**Budesonide nebuliser suspension for inhalation 0,25 mg/ml, 0,5 mg/ml**)

(Sugar free)

Read all of this leaflet carefully before you start using BUDAIR

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

What is in this leaflet

1. What BUDAIR is and what it is used for

BUDAIR contains the active ingredient budesonide. This belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.

BUDAIR is used to treat asthma (disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. Symptoms may include breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest).

It is also used to treat croup (infection of the upper airway, which obstructs breathing and causes a characteristic barking cough) in infants and children.

2. What you need to know before you use/give BUDAIR

Do not use/give your child BUDAIR if you or your child:

- are hypersensitive (allergic) to budesonide or any of the other ingredients in **BUDAIR** (listed in **section 6**)
- has tuberculosis of lungs, fungal and viral infection of airways (symptoms may include feeling of breathlessness, coughing up sputum, or in severe cases blood, chest tightness, and a general feeling of weakness).

Warnings and precautions

Take special care with BUDAIR

You or your child's facial skin may also become irritated when a nebuliser with face mask is used. To prevent irritation the facial skin should be washed with water after use of the face mask

To lower the risk of getting thrush, rinse the mouth out with water after taking / giving each dose.

Tell your or your child's doctor, if you or your child finds that your asthma pump is ineffective or more inhalations are required for relief of the symptoms. The dose of **BUDAIR** may need to be increased.

If your child is receiving **BUDAIR** check their height regularly to see if their growth is being affected by the treatment. Tell your child's doctor if you think they are not growing or their growth is slow.

Talk to your or your child's doctor before using/giving **BUDAIR** if you or your child has:

- lung infection.
- liver problems.

Contact your or your child's doctor if you or your child experience blurred vision or other visual disturbances.

If you are not sure if any of the above applies to you or your child, talk to your or their doctor or pharmacist before using or giving your child **BUDAIR**.

Other medicines and BUDAIR

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 medicines:

- Medicines to treat fungal infections (such as itraconazole and ketoconazole)
- HIV medicines (such as ritonavir or cobicistat-containing products)
- Steroid medicines
- Cimetidine (used to treat heartburn and stomach ulcers)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this **BUDAIR**.

Safety in pregnancy has not been reported.

It is important for both foetus and mother to maintain an adequate asthma treatment during pregnancy.

Driving and using machines

BUDAIR has no effect on ability to drive and use machines.

Blurred vision may occur, and you should be advised not to drive or operate machines until you know how BUDAIR affects you.

3. How to use BUDAIR

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

Always use or give your child **BUDAIR** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

BUDAIR should be put into a jet nebuliser and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece. The nebuliser should be connected to an air compressor with an adequate air flow (5-8 litres/minute), and the fill volume should be 2-4 ml.

Do not use an ultrasonic nebuliser with **BUDAIR.**

Your or your child's doctor will decide what dose of **BUDAIR** you should use or give to your child, depending on your or their condition and if you are using any other medicines.

The usual dose is:

Asthma

Adults: The initial dose is 0,5 -1 mg twice daily.

Children: The maintenance dose is 0,25 -0,5 mg twice daily.

Croup

The recommended dose for infants and children is 2 mg a day. This may be given all in one go, or 1 mg may be given followed by another 1 mg 30 minutes later.

Your doctor will tell you if you are required to mix **BUDAIR** with other solutions for nebulisation.

Instructions for using BUDAIR:

1. *Break off a plastic ampoule from the strip. Leave the rest in the aluminium pouch.*

   Note: Ampoules in an opened pouch should be used within three months.
2. *Shake the ampoule gently.*
3. *Hold upright and twist off the top of the ampoule to open it.*
4. *Place the open end of the ampoule firmly inside the nebuliser cup and squeeze slowly to put the liquid in the cup.*
5. *If the ampoule is empty throw it away. If there is remaining suspension in the ampoule, store it upright and protected from light.*

   Note: The remaining suspension must be used within 12 hours. Before using, shake the ampoule gently.
6. *Put the top back on the nebuliser cup.*
7. *Connect one end of the cup to the face mask or mouthpiece.*
8. *Connect the other end of the cup to the air pump.*
9. *Gently shake the cup.*
10. *Turn on the nebuliser and breathe in the mist calmly and deeply using the face mask or mouthpiece.* If you are using a face mask make sure the face mask fits tightly.
11. *You will know when your treatment is complete because the fine mist will stop coming out of your mask or mouthpiece.*
12. *How long it takes to nebulise all the medicine depends on the type of equipment you use. It will also depend on the amount of medicine to be used.*

13. *Rinse your mouth with water. Spit out the water. Do not swallow it. If you have used a face mask, wash your face as well.*
14. *After each use, you must wash the nebuliser cup and mouthpiece (or face mask) in warm soapy water and rinse well. After washing, dry these parts by connecting to the air outlet or the compressor and blow air through them.*

If you use or give your child more BUDAIR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre

It is important that you take the dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. If you use/give more **BUDAIR** than you should, contact your or your child's doctor or pharmacist for advice.

If you forget to use BUDAIR

If you forget to use/give a dose, skip the missed dose and take/give the next dose as usual. Do not use/give a double dose to make up for the forgotten individual doses.

If you stop using BUDAIR

Do not stop using/giving **BUDAIR** unless your or your child's doctor tells you to do so.

If you have any further questions on the use of this product, ask your or your child's doctor or pharmacist.

4. Possible side effects

BUDAIR can have side effects.

Not all side effects reported for **BUDAIR** are included in this leaflet. Should you or your child's general health worsen or if you or your child experiences any untoward effects while taking **BUDAIR**, please consult your or their doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using/giving your child BUDAIR and tell your or their doctor immediately or go to the casualty department at your or their nearest hospital:

- Swelling of your face, particularly around your mouth (with possible swelling of the lips, tongue, eyes, ears), rash, itching, contact dermatitis (a skin problem; symptoms may include red rash, itching, bumps, blisters), hives and bronchospasm (tightening of the muscles in the airways which causes wheezing). This may mean that you are having an allergic reaction.

These are all very serious side effects. If they occur, you or your child may have had a serious reaction to **BUDAIR.** You or your child may need urgent medical attention or hospitalisation.

Tell your or your child's doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bruising or bleeding easily;
- Glaucoma (condition that damages eye's optic nerve and may lead to blindness. Symptoms may include severe eye pain, feeling sick, being sick, seeing coloured rings around light, sudden blurred vision).

These are serious side effects. You may need urgent medical attention.

Tell your or your child's doctor if you notice any of the following:

Frequent side effects:

- Thrush (a fungal infection) in the mouth;
- Pneumonia (infection of the lung; symptoms may include fever, chills, shortness of breath, cough, phlegm and occasionally blood) in patients with chronic obstructive pulmonary disorder (a group of lung diseases that block airflow and make it difficult to breathe) patients;
- Coughing and a hoarse (harsh or strained) voice, sore throat.

Less frequent side effects:

- Slowing of the rate of growth of children and adolescents;
- Effect on the adrenal gland (a small gland next to the kidney);
- Anxiety, depression, psychomotor hyperactivity (symptoms may include emotional distress, restlessness, fast talking, fidgeting), sleep disorders, aggression, behavioural changes (predominantly in children);
- Tremor (shaking);
- Cataract (clouding of the lens of eye which leads to decrease in vision);
- Blurred vision;
- Dysphonia (abnormal voice);
- Muscle spasm;
- Hoarse voice (in children).

Frequency not known (cannot be estimated from available data):

- Nervousness;
- Restlessness.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurses. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **BUDAIR**.

5. How to store BUDAIR

- Store in the original container at or below 30 °C.
- Always store unopened ampoules in the aluminium pouch in order to protect from light. Ampoules in an open pouch should be used within 3 months.

  If you do not use a full ampoule for each dose, store the opened ampoule upright and protected from light. The remaining suspension in an opened ampoule should be used within 12 hours.
- Do not use after expiry date stated on the label / carton / ampoule.
- Return al unuesd medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systemsn (e.g. toilets).

6. Contents of the pack and other information

What BUDAIR contains

The active substance is budesonide.

BUDAIR 0,25 mg/ml

Each ampoule contains 0,5 mg of budesonide.

Sugar free

BUDAIR 0,5 mg/ml

Each ampoule contains 1,0 mg of budesonide.

Sugar free

The other ingredients are: Citric acid monohydrate, Edetate Sodium, Polysorbate 80, Sodium chloride, Sodium citrate, Nitrogen, Water for injection

What BUDAIR looks like and contents of the pack

Each plastic ampoule contains 2 ml off white coloured aqueous suspension. Strips of 5 ampoules are packed in a sealed printed aluminium pouch. Four aluminium pouches are packed in a printed unit carton of 20 ampoules.

Holder of Certificate of Registration

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