PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

BUDONEB 0,25 mg/ml (nebuliser suspension)

BUDONEB 0,5 mg/ml (nebuliser suspension)

Read this entire leaflet carefully before you start using BUDONEB.

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

BUDONEB is an aqueous suspension of budesonide buffered to pH 4,5.

BUDONEB 0,25 mg/ml (2 ml/ampoule): Each ml contains 0,25 mg of budesonide.

BUDONEB 0,5 mg /ml (2 ml/ampoule): Each ml contains 0,5 mg of budesonide.

The other ingredients are:

Citric acid, anhydrous, disodium edetate, polysorbate 80, sodium chloride, sodium citrate, water for injection.

BUDONEB is sugar free.

2. WHAT BUDONEB IS USED FOR:

BUDONEB is a steroid with local anti-inflammatory effects.

It is used for control of asthma in patients needing additional treatment with steroids and patients who are unable to use a pressurised metered dose inhaler or unable to inhale the medicine in powder form.

It is also used in infants and children with croup.

3. BEFORE YOU USE BUDONEB:

Do not use BUDONEB:

- if you are hypersensitive (allergic) to budesonide, or any of the other ingredients of BUDONEB
- if you have lung tuberculosis, fungal and viral infections in the airways
- safety and efficacy for children less than 12 months have not been established

Take special care with BUDONEB:

- not to be used for injection
- for use only in a nebuliser
- not suitable for use with ultrasonic nebulisers
- it is not intended for rapid relief of acute episodes of asthma where an inhaled short-acting bronchodilator is required
- patients with severely compromised liver function
- long term use may affect your vision.

Pregnancy and Breastfeeding:

Safety of inhaled BUDONEB taken during pregnancy is not known.

There is no information available on whether budesonide passes into breast milk.

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

Taking other medicines with BUDONEB:

No interactions between BUDONEB and other medicines used in the treatment of asthma have been observed.

Always tell your healthcare professional if you are taking or have recently taken any other medicine, including medicines obtained without a prescription.

(This includes complementary or traditional medicines.)

Some medicines may increase the effects of BUDONEB and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat, ketoconazole and itraconazole).

4. **HOW TO USE BUDONEB:**

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

Always use BUDONEB exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dose is usually given twice daily.

BUDONEB must be used with a jet nebuliser supplied with a mouthpiece or mask. The nebuliser should be connected to an air compressor with adequate air flow (5-8 ℓ/min) and filling volume 2-4 ml.

Initial dosage:

The usual dosage is:

Children 1- 6 years and older: 0,25 – 0,5 mg daily.

Adults: 1 – 2 mg daily.

A higher dose may be considered for patients taking oral steroids or for patients in whom a greater therapeutic effect is desired.

Maintenance dose

The dosage of BUDONEB is individual.

Children: 0,25 – 2 mg daily.

Adults: 0,5 – 4 mg daily.

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

Croup

Infants and children: One 2 mg dose as a single administration or two 1 mg doses given 30 minutes apart.

BUDONEB may be mixed with 0,9 % sodium chloride solution and with solutions of terbutaline, salbutamol, sodium cromoglycate or ipratropium.

The mixture should be used within 30 minutes.

Instruction for correct use of BUDONEB:

For use only in a nebuliser. Not to be used for injection.

Shake the contents gently using a swirling motion.

Hold the single dose unit (2 ml /ampoule) upright and open by twisting off the wing.

Place the open end of the unit well into the reservoir of the nebuliser and squeeze slowly.

Any suspension remaining must be discarded.

Single dose units (2 ml /ampoule) in an opened pouch should be used within 3 months.

After use:

Rinse the mouth out with water after inhaling the prescribed dose to minimise the risk of thrush.

Wash the facial skin with water after using the face mask to prevent irritation.

Cleaning instructions:

Adequately clean and maintain the nebuliser according to the manufacturer's instructions.

If you use more BUDONEB than you should:

In the event of an overdose, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Discontinue treatment and take appropriate measures to avoid stress situations.

Effects when treatment with BUDONEB is stopped:

When tapering off systemic steroids some patients experience withdrawal symptoms e.g. joint &/or muscle pain, lack of energy, depression or even decreased lung function.

5. POSSIBLE SIDE EFFECTS:

BUDONEB can have side effects. Not all side effects reported for BUDONEB are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking BUDONEB please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.

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

Inform your doctor if you experience any of the following side effects:

- depression
- behavioural disturbances
- bronchospasm
- mild irritation in the throat
- hoarseness
- coughing
- oral thrush
- nervousness
- restlessness
- skin irritations
- rash and bruising
- pain in muscles and joints
- tiredness
- headache
- nausea
- vomiting

- rhinitis
- eczema
- blurred vision

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

6. STORING AND DISPOSING OF BUDONEB:

Keep all medicines out of the reach and sight of children.

Store at or below 25 °C.

Keep unused ampoules in the pouch. Once the pouch is opened, the unused ampoules must be protected from light by keeping the pouch closed.

The ampoules in the opened pouches should be used within three months from date of first opening the pouch.

The ampoule must be swirled before use.

The ampoule once opened will not be re-used again. Any suspension not used immediately should be discarded. Return all unused medicine to your pharmacist.

7. PRESENTATION OF BUDONEB:

3 ml single-dose low density polyethylene polymer, Purell PE 3020 D unit dose ampoules in strips of 5 ampoules per strip, overwrapped in a tri-laminate foil pouch (consists of an outer layer-polyester film, middle layer-aluminium foil and inner layer- polyethylene).

One strip is packed per foil pouch.

Four foil pouches are packed into an outer carton.

Each carton contains 20 clear, translucent LDPE resin ampoules of 2 ml nebuliser suspension.

8. IDENTIFICATION OF BUDONEB:

White to off-white suspension in single-dose plastic ampoule unit with a twist off top, for use in a nebuliser.

9. REGISTRATION NUMBER:

BUDONEB 0,25 mg/ml: 42/21.5.1/0953

BUDONEB 0,5 mg/ml: 42/21.5.1/0954

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

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2090

11. DATE OF PUBLICATION:

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