

**Terbutaline sulfate****Bricanyl<sup>®</sup> 2.5 mg/mL (5 mg/2 mL)****Solution for Nebulizing**

Single dose plastic units

Selective Beta-2-Adrenoreceptor Agonist

**1. FORMULATION**

1 mL contains: Terbutaline sulfate 2.5 mg.

**2. PHARMACEUTICAL FORM**

Solution for nebulization in single dose units of 2 mL.

Terbutaline sulfate (BRICANYL) solution for nebulization is isotonic and contains no preservatives.

**3. CLINICAL PARTICULARS****3.1 Therapeutic Indications**

Bronchial asthma. Chronic bronchitis, emphysema and other lung diseases where bronchospasm is a complicating factor.

**3.2 Dosage and method of administration**

Inhaled bronchodilators should, as initial therapy, be used as required rather than regularly.

Terbutaline sulfate (BRICANYL) solution for nebulization is to be used in nebulizers with or without assisted breathing in acute or subacute disorders where conventional inhalers prove unsatisfactory, and in maintenance therapy in severe broncho-obstructive conditions.

Dosage should be individual.

*Body weight >20 kg:* 5 mg (1 single dose unit, 2 mL) is inhaled up to 4 times in a 24 h period.*Body weight <20 kg:* 2.5 mg (1/2 single dose unit, 1 mL) is inhaled up to 4 times in a 24 h period. An opened single dose unit should be used within 24 hours.**3.3 Contraindications**

Hypersensitivity to any of the ingredients.

### **3.4 Special warnings and precautions for use**

The patient's inhalation technique should be checked regularly, and the optimal dose of Terbutaline sulfate (BRICANYL) should be adjusted for each nebulizer.

If a previously effective dosage regimen no longer gives the same symptomatic relief the patient should seek medical advice as soon as possible as this could be the sign of worsening asthma and repeated inhalations of  $\beta_2$ -agonists must then not delay reassessment of the asthma therapy.

As for all  $\beta_2$ -agonists caution should be observed in patients with thyrotoxicosis and in patients with severe cardiovascular disorder, such as ischemic heart disease, tachyarrhythmias or severe heart failure.

Due to the hyperglycemic effects of  $\beta_2$ -agonists, additional blood glucose controls are recommended initially in diabetic patients.

Potentially serious hypokalemia may result from  $\beta_2$ -agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalemic effect may be potentiated by concomitant treatments (see section 3.5 Interactions with other medicinal products and other forms of Interaction.). It is recommended that serum potassium levels are monitored in such situations.

### **3.5 Interaction with other medicinal products and other forms of interaction**

Beta-receptor blocking agents (including eye-drops), especially those which are non-selective, may partly or totally inhibit the effect of beta-receptor stimulants.

Hypokalemia may result from  $\beta_2$ -agonist therapy and may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics (see 3.4 Special warnings and precautions for use).

### **3.6 Pregnancy and lactation**

No teratogenic effects have been observed in patients or in animals. However, caution is recommended during the first trimester of pregnancy.

Terbutaline passes over to breast milk but an influence on the child is unlikely with therapeutic doses.

Transient hypoglycemia has been reported in newborn preterm infants after maternal  $\beta_2$ -agonist treatment.

### 3.7 Effects on ability to drive and use machines

Terbutaline sulfate (BRICANYL) does not affect the ability to drive or use machines.

### 3.8 Undesirable effects

The frequency of adverse reactions is low at the recommended dose. Terbutaline given by inhalation is unlikely to produce significant systemic effects when given in recommended doses because pharmacologically active concentrations of the drug are not achieved in the systemic circulation. Adverse reactions which have been recorded, e.g. tremor, headache, nausea, tonic muscle cramps, tachycardia and palpitations, are all characteristic of sympathomimetic amines. The majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment.

As for all  $\beta_2$ -agonists, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles have been rarely reported.

Urticaria and exanthema may occur.

Sleep disturbances and behavioural disturbances, such as agitation, hyperactivity and restlessness, have been observed.

In rare cases, through unspecified mechanisms, drugs for inhalation may cause bronchospasm.

### 3.9 Overdose

*Possible symptoms and signs:* Headache, anxiety, tremor, nausea, tonic muscle cramps, palpitations, tachycardia and cardiac arrhythmias. A fall in blood pressure sometimes occurs.

*Laboratory findings:* Hyperglycaemia and lactacidosis sometimes occur.  $\beta_2$ -agonists may cause hypokalemia as a result of redistribution of potassium.

*Treatment of overdose:* Usually no treatment is required. If it can be suspected that significant amounts of terbutaline sulfate have been swallowed, the following measures should be considered:

Gastric lavage, activated charcoal. Determine acid-base balance, blood glucose and electrolytes. Monitor heart rate and rhythm and blood pressure. The preferred antidote for overdose with Terbutaline sulfate (BRICANYL) is a cardioselective beta-receptor blocking agent, but beta-receptor blocking drugs should be used with caution in patients with a history of bronchospasm. If the  $\beta_2$ -mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

## **4. PHARMACOLOGIC PROPERTIES**

### **4.1 Pharmacodynamic properties**

Pharmaco-therapeutic group: selective  $\beta_2$ -agonist, terbutaline, ATC code: R03A C03

Terbutaline is an adrenergic agonist which predominantly stimulates  $\beta_2$ -receptors, thus producing relaxation of bronchial smooth muscle, inhibition of the release of endogenous spasmogens, inhibition of edema caused by endogenous mediators and increased mucociliary clearance.

Inhaled terbutaline acts within a few minutes and has a duration for up to 6 hours.

### **4.2 Pharmacokinetic properties**

Terbutaline is metabolized mainly by conjugation with sulphuric acid and excreted as the sulfate conjugate. No active metabolites are formed.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1. Incompatibilities**

Terbutaline sulfate (BRICANYL) solution for nebulization should not be mixed with alkaline solutions, i.e. solutions with a pH higher than 7.0.

### **5.2 Shelf-life**

Please refer to outer carton.

Single dose units in opened envelopes should be used within 3 months.

### **5.3 Special precautions for storage**

Store at a temperature not exceeding 30°C. Protect the ampoules from light.

### **5.4 Availability**

Terbutaline sulfate (BRICANYL) 2.5mg/mL – Box of 20 x 2 mL

### **5.5 Instruction for use, handling and disposal**

### **How should Terbutaline sulfate (BRICANYL) solution for nebulization be taken?**

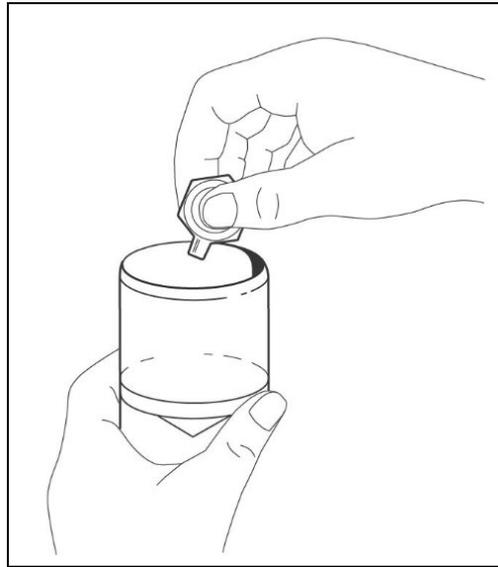
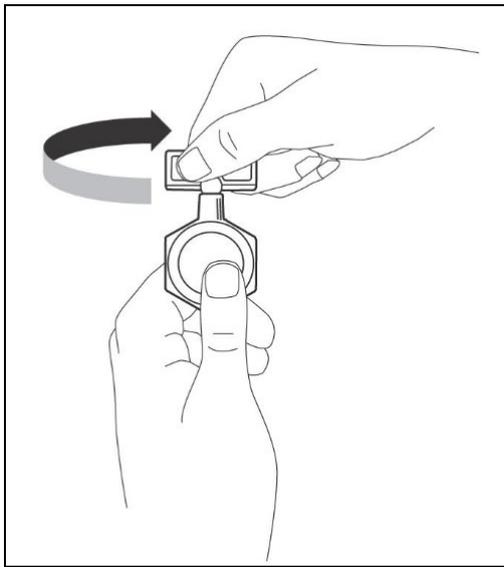
The dosage is individual. Follow your doctor's directions carefully. They may differ from the information in this leaflet.

Terbutaline sulfate (BRICANYL) solution for nebulization can only be used in a nebulizer. Be sure you know how to use your nebulizer before you start taking this medicine.

You usually get an effect of Terbutaline sulfate (BRICANYL) within a few minutes. The effects lasts up to 6 hours.

### **Instructions for use**

1. Hold the single dose unit upright (see picture) and open by twisting off the wing.
2. Place the open end of the unit well into the reservoir of the nebulizer, and squeeze slowly.



### **Note**

1. If you use a face mask, make sure that the mask fits tightly while you are inhaling.
2. Opened single dose units should be used within 24 hours.

Do not use units from a foil envelope that has been open for 3 months or more.

### **Cleaning**

The nebulizer chamber and the mouthpiece, or the face mask, should be cleaned after each use. Wash the parts in hot tap water using a mild detergent or according to the instructions supplied by the manufacturer of the nebulizer. Rinse well and dry by connecting the nebulizer chamber to the compressor or an air inlet.

### **CAUTION**

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, please report to the Food and Drug Administration (FDA) at [www.fda.gov.ph](http://www.fda.gov.ph) and to AstraZeneca at [patientsafety.ph@astrazeneca.com](mailto:patientsafety.ph@astrazeneca.com). The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

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