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Terbutaline sulfate

Bricanyl® 2.5 mg Tablet

Anti-asthma (Selective beta-2-adrenoreceptor agonist)

1. FORMULATION

One tablet contains 2.5 mg terbutaline sulfate

2. PHARMACEUTICAL FORM

Tablet.

3. CLINICAL PARTICULARS

3.1 Therapeutic indications

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

3.2 Dosage and method of administration

Terbutaline sulfate (BRICANYL) tablets should be used as maintenance therapy in asthma and other pulmonary diseases where bronchospasm is a complicating factor. Preterm labour.

Dosage should be individually titrated.

Bronchospasm:

Adults: During the first 1-2 weeks 2.5 mg (1 tablet) 3 times in a 24 h period is recommended. The dose may then, if necessary, be increased to 5 mg (2 tablets) 3 times in 24 hours.
Children: 0.075 mg/kg body weight 3 times in 24 hours.
Suitable dosage:
20 kg: ¼-½ tablet 3 times in 24 hours.
20-30 kg: ½-1 tablet 3 times in 24 hours.
>30 kg: 1-2 tablets 3 times in 24 hours.

Preterm labour:
The drug must be individually titrated. Pulse rate and blood pressure should be carefully monitored during treatment. Initially 5 ug/min I.V. of Terbutaline sulfate (BRICANYL) solution for injection could be given as an infusion during 20 minutes. The dose can then be increased by 2.5 ug/min at 20 minutes intervals until contractions stop. More than 10 ug/min should seldom be given and 20 ug/min should not be exceeded. Let the infusion continue for 1 h at the chosen infusion rate, and then decrease the rate of infusion in steps of 2.5 ug/min at 20 minutes interval down to the lowest maintenance dose that produces continued suppression of the contractions. Keep the infusion at this rate for 12 h and then continue with oral maintenance therapy (5 mg x 3).

The oral treatment should be continued until the end of the 36^{th} week of pregnancy. As an alternative treatment, subcutaneous injections (0.25 mg four times in a 24 h period) could be given for a few days before oral treatment is started.

3.3 Contraindications
Hypersensitivity to any of the ingredients.

3.4 Special warnings and precautions for use
As for all β_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 β_2-agonists, additional blood glucose controls are recommended initially in diabetic patients.

Potentially serious hypokalemia may result from β_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 3.5 Interactions with other medicinal products and other forms of interactions). It is recommended that serum potassium levels are monitored in such situations.

3.5 Interactions with other medicinal products and other forms of interactions
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 β_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 Use during 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 β_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 intensity of the adverse reactions depends on dosage and route of administration. An initial dose titration will often reduce the adverse reactions. Adverse reactions which have been recorded, e.g. tremor, headache, 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 β_2-agonist, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystole have been rarely reported

Urticaria and exanthema may occur.

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

3.9 Overdosage

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: Hyperglycemia and lactacidosis sometimes occur. β_2-agonists may cause hypokalemia as a result of redistribution of potassium.

Treatment of overdosage:
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 overdosage 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 β_2-mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties
Phamaco-therapeutical group: selective β_2-agonist, terbutaline, ATC code: R03C C03

Terbutaline is an adrenergic agonist which predominantly stimulates β_2-receptors, thus producing relaxation of bronchial smooth muscle, inhibition of the release of endogenous spasmogens, inhibition of edema caused by endogenous mediators, increased mucociliary clearance and relaxation of the uterine muscle.

The bronchodilating effect of Terbutaline sulfate (BRICANYL) tablets has in clinical trials been shown to have a duration for up to 8 hours.

4.2 Pharmacokinetic properties
There is a considerable first-pass metabolism in the intestinal wall and in the liver. The bioavailability is about 10% and increases to about 15% if terbutaline is taken on an empty stomach. Maximum plasma concentration of terbutaline is reached within 3 hours. Terbutaline is metabolized mainly by conjugation with sulphuric acid and excreted as the sulfate conjugate. No active metabolites are formed.

4.3 Preclinical safety data
The major toxic effect of terbutaline, observed in toxicological studies, is focal myocardial necrosis. This type of cardiotoxicity is a well known class-effect, and the effect of terbutaline is similar to or less pronounced than that of other beta-receptor agonists. Terbutaline has been used extensively over many years for the relief of bronchospasm without identifying any areas of concern.

5. PHARMACEUTICAL PARTICULARS

5.1 Incompatibility
Not applicable

5.2 Shelf life
Please refer to outer carton.

5.3 Special Precautions for Storage
Store at a temperature not exceeding 30°C.

5.4 Availability
Terbutaline sulfate (BRICANYL) 2.5 mg Tablet – Box of 500's

6. REGISTRATION NUMBER
DR-XY39882

7. DATE OF FIRST AUTHORIZATION
11 August 2011

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 and to AstraZeneca at patientsafety.ph@astrazeneca.com. The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

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