

NEW ZEALAND DATA SHEET

NAME OF MEDICINE

BRICANYL TURBUHALER
terbutaline sulphate 250 µg/dose.

PRESENTATION

TURBUHALER 250 µg/dose - white to off-white, rounded granules, which disintegrate to a fine powder upon slight pressure, filled into a specially designed inhaler made of plastic materials. The colour of the turning grip is light blue. Contains 200 actuations. Each actuation releases 250 µg terbutaline sulphate. On the bottom of the turning grip, a Braille code for identification of terbutaline is embossed.

USES

ACTIONS

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 oedema caused by endogenous mediators and increased mucociliary clearance.

The bronchospasmolytic effect (time to onset, time to maximum effect and duration) and the extent of metabolism are dependent on the route of administration of terbutaline. The time to maximum effect is 30-60 minutes following inhalation.

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

PHARMACOKINETICS

Terbutaline is delivered to the prime site of action in the lungs by TURBUHALER administration.

About 20-30% of the metered dose is deposited in the lungs at a normal inhalation flow rate.

Terbutaline is metabolised mainly by conjugation with sulphuric acid and excreted as the sulphate conjugate.

No active metabolites are formed. Inhaled terbutaline is absorbed unchanged from the respiratory tract.

The presence of the two phenolic hydroxyl groups in the meta-positions confers resistance to metabolism by the enzyme catechol-o-methyl transferase.

In normal adult men and women, the terminal elimination phase has a half-life of around 15 hours.

After administration by inhalation between 2-37% of the delivered terbutaline was recovered in faeces and 3-35% in urine.

Excretion of terbutaline sulphate and its metabolites is essentially complete within 72-96 hours after a single parenteral or oral dose.

As terbutaline is largely excreted in urine, caution should be exercised in patients with renal impairment.

No dosage adjustments are required in the elderly provided hepatic and renal function are normal.

INDICATIONS

Relief of bronchospasm occurring in bronchial asthma, bronchitis and other bronchopulmonary conditions where bronchospasm is a complicating factor.

Acute prophylaxis in situations known to induce bronchospasm, e.g. exercise-induced asthma.

DOSAGE AND ADMINISTRATION

If long term use of terbutaline is proposed, particularly if the patient is asked to take terbutaline in conjunction with other medications, objective pulmonary function testing (for example, by peak flow meter or spirometer) may be useful as part of assessment of the efficacy of treatment.

BRICANYL TURBUHALER is inspiratory flow driven and hence there is no need to coordinate the release of the dose and the inhalation as with a pressurised inhaler. When inhaling, the substance follows the inspired air into the airways. Treatment with BRICANYL TURBUHALER is effective even during an acute asthmatic attack.

The dosage of inhaled terbutaline via BRICANYL TURBUHALER should be individualised. BRICANYL TURBUHALER should be used as required rather than regularly.

Adults and children over 12 years: 250-500 µg as required. In severe cases the single dose may be increased to 1.5 mg. The total dose should not exceed 6 mg in 24 hours.

Children (3-12 years): 250-500 µg as required. In severe cases the single dose may be increased to 1.0 mg. The total dose should not exceed 4 mg in 24 hours.

When prescribing BRICANYL TURBUHALER to young children it is necessary to ascertain that they can follow the instructions for use.

INSTRUCTION FOR THE CORRECT USE OF TURBUHALER

TURBUHALER is inspiratory flow-driven which means that, when the patient inhales through the mouthpiece, the substance will follow the inspired air into the airways.

Note: It is important to instruct the patient

- to carefully read the instructions for use in the information leaflet which is packed with each inhaler
- to breathe in forcefully and deeply through the mouthpiece to ensure that an optimal dose is delivered to the lungs
- never to breathe out through the mouthpiece.

The patient may not taste or feel any medication when using TURBUHALER due to the small amount of drug dispensed.

CONTRAINDICATIONS

Hypersensitivity to sympathomimetic amines.

WARNINGS AND PRECAUTIONS

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. Repeated inhalations of beta₂-agonists must then not delay reassessment of the asthma therapy.

As for all beta₂-agonists caution should be observed in patients with thyrotoxicosis and in patients with severe cardiovascular disorders, such as ischaemic heart disease, tachyarrhythmias or severe heart failure.

Due to the hyperglycaemic effects of beta₂-agonists, additional blood glucose controls are recommended initially in diabetic patients.

Potentially serious hypokalaemia may result from beta₂-agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalaemic effect may be potentiated by concomitant treatments (see Interactions). It is recommended that serum potassium levels are monitored in such situations.

BRICANYL should be used with caution if susceptibility to sympathomimetic amines is likely to be increased, for instance in patients with hyperthyroidism not yet under adequate control.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES

BRICANYL TURBUHALER does not affect the ability to drive or use machines.

PREGNANCY AND LACTATION

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

Although terbutaline is secreted into breast milk, and milk concentrations are approximately those in maternal plasma, two individual case studies indicate that the infant is likely to receive 0.2 - 0.7% of the maternal dose (0.4 and 0.7 µg/kg/day respectively), depending (for example) on the time of feeding in relation to administration of the medicine. In the 4 infant studies this did not result in any signs of beta-adrenoceptor stimulation.

Transient hypoglycaemia has been reported in newborn preterm infants after maternal beta₂-agonist treatment.

ADVERSE 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.

MORE COMMON REACTIONS

Commonly observed side effects include tremor, headache, nausea, tonic muscle cramps, nervousness, tachycardia and palpitations. The majority of these effects reverse spontaneously within the first 1-2 weeks of treatment.

LESS COMMON REACTIONS

Cardiovascular: Ectopic beats.

Gastrointestinal: Vomiting, bad taste, diarrhoea.

General: Sweating.

Musculo-skeletal: Muscle twitching.

Nervous system: Drowsiness, dizziness, sleep disturbances and behavioural disturbances such as agitation, hyperactivity and restlessness.

Dermatological: Urticaria and exanthema may occur.

Other: In rare cases, through unspecified mechanisms, medicines for inhalation may cause bronchospasm.

As for all beta₂-agonists, cardiac arrhythmias, eg. atrial fibrillation, supraventricular tachycardia and extrasystoles have been rarely reported.

INTERACTIONS

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

Hypokalaemia may result from beta₂-agonist therapy and may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics (see Warnings and Precautions).

OVERDOSAGE

Possible symptoms and signs: headache, anxiety, tremor, nausea, insomnia, 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 hypokalaemia as a result of redistribution of potassium.

TREATMENT OF OVERDOSAGE

Usually no treatment is required. If it is suspected that significant amounts of terbutaline sulphate 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 BRICANYL is a cardioselective beta-receptor blocking agent, but beta-receptor blocking medicines should be used with caution in patients with a history of bronchospasm. If the beta₂-mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

PHARMACEUTICAL PRECAUTIONS**STORAGE CONDITIONS**

BRICANYL TURBUHALER should be stored at temperatures not exceeding 30°C, with the cover on.

SHELF-LIFE

24 months.

CONTAINER

BRICANYL TURBUHALER is a multidose, inspiratory flow-driven, metered dose powder inhaler. The device is made of plastic parts.

MEDICINE CLASSIFICATION

Prescription Medicine

PACKAGE QUANTITIES

250 µg/dose, 200 doses

FURTHER INFORMATION

Chemical name: 1-(3,5-Dihydroxyphenyl)-2-t-butylaminoethanol sulphate.

BRICANYL TURBUHALER contains only the active substance terbutaline sulphate and is free from propellants, lubricants, preservatives, carrier substances or other additives.

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