Due to the hyperglycemic effects of β2-agonists, additional blood glucose controls are recommended initially in diabetic patients.

Potentially serious hypokalemia may result from β2-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 Interactions). It is recommended that serum potassium levels are monitored in such situations.

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 β2-agonist therapy and may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics (see “Warnings and Precautions”).

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 β2-agonist treatment.

Effects on ability to drive and use machines
Bricanyl does not affect the ability to drive or use machines.

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, tonic muscle cramps and palpitations,
are all characteristic of sympathomimetic amines. The majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment. 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.

**Overdosage**

Possible symptoms and signs: Headache, anxiety, tremor, tonic muscle cramps, palpitations, arrhythmia. A fall in blood pressure sometimes occurs. Laboratory findings: Hyperglycaemia and lactacidae sometimes occur. ß2-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 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 overdosage with 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 ß2-mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expender should be given.

**Pharmacodynamic properties**

Terbutaline is an adrenergic agonist which predominantly stimulates ß2-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.

**Pharmacokinetic properties**

About 10% of the metered dose is deposited in the lungs. Terbutaline is metabolized mainly by conjugation with sulphuric acid and excreted as the sulphate conjugate. No active metabolites are formed.

**List of excipients**

Sorbitan trioleate, trichlorofluoromethane, dichlorotetrafluoroethane, dichlorodifluoromethane.

**Special precautions for storage**

Do not store above 25ºC.

**Shelf life**

Please see outer pack

**Package**

Please see outer pack

**Date or revision**

October 21, 1997

**Instructions for use**

1. Remove the protective cap
2. Shake thoroughly to mix the contents of the inhaler properly.
3. Close your lips around the mouthpiece.
4. Breathe out calmly through the mouthpiece.
5. Breathe in and release a dose. After starting to breathe in slowly and deeply through your mouth, press the inhaler firmly to release the dose and continue to breathe in.
6. Hold your breath as long as possible preferably for 10 seconds, and then breathe out.

If a further dose is prescribed, shake the inhaler again and repeat points 2-6.

**Important**

Bricanyl exerts its action in the lungs. It is therefore important that the dose is released at the same time as you breathe in to allow as much as possible of the dose to penetrate deep into the lungs. You may check in a mirror that the aerosol liquid, which looks like a mist, does not leak out through the mouth or the container.

**NB**

Follow you doctors directions and do not use Bricanyl inhaler more often than prescribed. Contact your doctor if you find the effect strongly reduced.

**Children**

Children should only use Bricanyl on a doctors prescription and the always under supervision of an adult.
Cleaning
Clean the plastic parts regularly (weekly). Remove the aerosol container. Wash the plastic parts in warm – not hot – water, with the addition of a mild detergent if necessary. Allow the plastic parts to dry completely and then replace the aerosol container.

Contents under pressure
The inhaler container is filled under pressure. Do not puncture or throw the container into an incinerator. Using or storing near an open flame or heating above 40°C may cause the container to burst. You can check how much there is left in the aerosol container by placing it in a bowl of water.
Always keep a new Bricanyl metered dose aerosol in reserve!