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).

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 Turbuhaler does not affect the ability to drive or use machines.

Undesirable effects
The frequency of adverse reactions is low. 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 lactacido-sis sometimes occur. ß2-agonists may cause hypo-kalemia 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 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 expander 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 20-30% of the metered dose is deposited in the lungs at a normal inhalation flow rate. Terbutaline is metabolized mainly by conjugation with sulphuric acid and excreted as the sulphate conjugate. No active metabolites are formed.

**List of excipients**
Bricanyl Turbuhaler contains only the active substance terbutaline sulphate.

**Special precautions for storage**
Do not store above 30oC. Should be stored with the cover tightened.

**Shelf Life**
Please see outer pack.

**Pack Size**
Please see outer pack.

**Date of revision**
October 22, 1997

**How to use Bricanyl Turbuhaler**
Turhuhaler is a multidose inhaler from which the drug is administered without the use of additives. When you breathe in through Turbuhaler the powder is delivered to the lungs. It is therefore important that you inhale forcefully and deeply through the mouthpiece.

Turhuhaler is very easy to use. Simply follow the instructions given below.
1. Unscrew and lift off the cover.
2. Hold the inhaler upright with the grip downwards. Load the inhaler with a dose by turning the grip as far as it will go and then back to the original position.
3. Breathe out. Do not breathe out through the inhaler.
4. Place the mouthpiece between your teeth, close your lips and breathe in forcefully and deeply through your mouth. Do not chew or bite hard on the mouthpiece.
5. Before breathing out, remove the inhaler from your mouth. If more than one dose has been prescribed, repeat steps 2-5.
6. Replace the cover.

**Note!**
Never breathe out through the mouthpiece. Always replace the cover properly after use. As the amount of the powder dispensed is very small, you may not be able to taste it after inhalation. However, you can still be confident that the dose has been inhaled if you have followed the instructions.
Cleaning
Clean the outside of the mouthpiece regularly (weekly) with a dry tissue.
Do not use water for cleaning the mouthpiece.

Special precautions for storage
The inhaler should be stored with the cover tightened on. Do not store above 30°C.

Information regarding Braille
For sight impaired, there is an identification figure according to the international Braille system at the bottom of the turning grip. This figure makes it possible to identify different medicines in Turbuhaler.
For Bricanyl Turbuhaler the identification figures is “1” with the following configuration:

How do you know when the inhaler is empty?
When a red mark can first be seen in the indicator window there are approximately 20 doses left. When the red mark has reached the lower edge of the window the inhaler is empty. The sound heard as you shake the inhaler is not produced by the medication but by a drying agent.