Contraindications
Hypersensitivity to any of the ingredients.

Special warnings and precautions for use
As for all β2-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 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 intensity of the adverse reactions depends on dosage and route of administration. 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.

Overdosage
Possible symptoms and signs: Headache, anxiety, tremor, tonic muscle cramps, palpitations, arrhythmia. A fall in blood pressure sometimes occurs. Laboratory findings: Hyperglycemia and lactic acidosis sometimes occur. β2-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 β2-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 β2-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 Bricanyl elixir has in clinical trials been shown to have a duration for up to 8 hours.

Pharmacokinetic properties
There is a considerable first-pass metabolism in the intestinal wall and in the liver. The bioavailability is around 10% and increases to around 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 sulphate conjugate. No active metabolites are formed.

List of excipients
Citric acid, disodium edetate, ethanol, glycerol, sodium hydroxide, sorbitol, sodium benzoate, flavour lemon limette, flavour raspberry, water.

Special precautions for storage
Do not store above 30°C.

Shelf life
Please see outer pack.

Pack size
Please see outer pack.