Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bricanyl Turbohaler 500 micrograms per metered dose, inhalation powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 500 micrograms of Terbutaline Sulphate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder
Product imported from the UK:
White to off white spherical particles which break into a fine powder on inhalation, contained in a plastic multi-dose breath-actuated metered dose powder inhaler.

4 CLINICAL PARTICULARS

Terbutaline is a selective β2-adrenergic agonist recommended for the relief and prevention of bronchospasm in bronchial asthma and in chronic bronchitis and other bronchopulmonary disorders in which bronchospasm is a complicating factor.

4.2 Posology and method of administration

Adults and Children: One inhalation (500 micrograms) (metered dose) as required. Not more than 4 inhalations should be necessary in any 24 hour period.

Elderly: Dosage as for adults.

Instructions for use and cleaning are provided in the Patient Information Leaflet, which can be found in each pack.

4.3 Contraindications

Bricanyl preparations are contra-indicated in patients with a history of sensitivity to terbutaline sulphate.

4.4 Special warnings and precautions for use

Patients should be instructed in proper use and their inhalation technique checked regularly.

Care should be taken in patients suffering from myocardial insufficiency or thyrotoxicosis.

Due to the hyperglycaemic effects of β2-stimulants, additional blood glucose measurements are initially recommended when Bricanyl therapy is commenced in diabetic patients.

Cardiovascular effects may be seen with sympathomimetic drugs, including Bricanyl. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with beta agonists. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving Bricanyl should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Potentially serious hypokalaemia may result from β_2-agonist therapy, mainly with parenteral or nebulised administration. Particular caution is advised in acute severe asthma as this effect may be augmented by hypoxia. The hypokalaemic effect may be potentiated by concomitant treatment with xanthine derivatives, corticosteroids and/or diuretics. It is recommended that serum potassium levels are monitored in such situations.

4.5 Interaction with other medicinal products and other forms of interaction

Beta-blocking agents (including eye drops), especially the non-selective ones such as propranolol, may partially or totally inhibit the effect of β2- stimulants. Therefore, Bricanyl preparations and non-selective β-blockers should not normally be administered concurrently. Bricanyl should be used with caution in patients receiving other sympathomimetics.

Hypokalaemia may result from β2-agonist therapy and may be potentiated by concomitant treatment with xanthine derivatives, corticosteroids and diuretics *(see Section 4.4, Special Warnings and Precautions for use).*

4.6 Fertility, pregnancy and lactation

Although no teratogenic effects have been observed in animals or in patients, Bricanyl should only be administered with caution during the first trimester of pregnancy.

Terbutaline is secreted via breast milk but any effect on the infant is unlikely at therapeutic doses.

Transient hypoglycaemia has been reported in newborn preterm infants after maternal β2-agonist treatment.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The frequency of side-effects is low. Side-effects which have been recorded such as tremor, headache, nausea, tonic cramp, mouth and throat irritation, tachycardia and palpitations are all characteristic of sympathomimetic amines. A few patients feel tense; this is also due to the effects on skeletal muscle and not to direct CNS stimulation. Whenever these side-effects have occurred, the majority have usually been spontaneously reversible within the first week of treatment. As with other β_2-agonists, tremor is dose related.

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

Tachycardia, with or without peripheral vasodilation, has been rarely reported during β_2-agonist therapy. Cardiac arrhythmias, including atrial fibrillation, supraventricular tachycardia and extrasystoles, have been reported in association with β_2-agonists, usually in susceptible patients. Myocardial ischaemia may occur; the incidence is unknown* (see section 4.4).

Potentially serious hypokalaemia may result from β_2-agonist therapy. (See also Section 4.4, Special Warnings and Precautions for use.)

In rare cases, through unspecified mechanisms, paradoxical bronchospasm may occur, with wheezing immediately after inhalation. This should be immediately treated with a rapid-onset bronchodilator. Bricanyl therapy should be discontinued and, after assessment, an alternative therapy initiated.

Hypersensitivity reactions, including angioedema, urticaria, exanthema, bronchospasm, hypotension and collapse, have been very rarely reported with β_2-agonist therapy.

*reported spontaneously in post-marketing data therefore frequency regarded as unknown

4.9 Overdose

i) Possible symptoms and signs: Headache, anxiety, tremor, nausea, tonic cramp, palpitations, tachycardia and arrhythmia. A fall in blood pressure sometimes occurs. Laboratory findings: Hypokalaemia, hyperglycaemia and metabolic acidosis sometimes occur.

ii) Treatment:
Mild and moderate cases: Reduce the dose.
Severe cases: Gastric lavage, administration of activated charcoal (where suspected that significant amounts have been swallowed). Determination of acid-base balance, blood sugar and electrolytes, particularly serum potassium levels. Monitoring of heart rate and rhythm and blood pressure. Metabolic changes should be corrected. A cardioselective β-blocker (e.g. metoprolol) is recommended for the treatment of arrhythmias causing haemodynamic deterioration. The β-blocker should be used with care because of the possibility of inducing bronchoconstriction: use 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Selective β2-agonist, terbutaline,
ATC code: R03A C03.

Terbutaline sulphate is an adrenergic agonist which predominantly stimulates β2-receptors, thus producing relaxation of bronchial smooth muscle, inhibition of the release of endogenous spasmogens, inhibitions of oedema caused by endogenous mediators and increased mucociliary clearance.

Inhaled terbutaline acts within a few minutes and has a duration for up to 6 hours. Treatment with Bricanyl Turbohaler is effective even during an acute asthma attack.

5.2 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.

5.3 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C

Replace the cover properly after use

6.5 Nature and contents of container

Bricanyl Turbohaler consists of a number of assembled plastic details, the main parts being the dosing mechanism, the drug substance store, the desiccant store and the mouthpiece. The inhaler is protected by an outer tubular cover screwed onto a bottom plate.

Each over labelled inhaler contains 100 metered doses.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

McDowell Pharmaceuticals
4 Altona Road
Lisburn
BT27 5QB
Northern Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1473/29/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd October 2009

10 DATE OF REVISION OF THE TEXT

February 2011