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:
Multi-dose breath-actuated metered dose powder inhaler. White to off white spherical particles which break into a fine powder on inhalation.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Terbutaline is a selective beta$_2$-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.

With each inhalation a fraction of the delivered dose will be deposited in the oral cavity. To minimize unnecessary systemic exposure to terbutaline, the patients should be advised to, when possible, rinse their mouth after each use.

If a previously effective dosage regimen no longer gives the same symptomatic relief, the patient should urgently seek further medical advice. Consideration should be given to the requirements for additional therapy (including increased dosages of anti-inflammatory medication). Severe exacerbations of asthma should be treated as an emergency in the usual manner.

As for all beta$_2$-agonists caution should be observed in patients with thryotoxicosis.

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.
Due to the positive inotropic effect of $beta_2$-agonists, these drugs should not be used in patients with hypertrophic cardiomyopathy.

Due to the hyperglycaemic effects of $beta_2$-agonists, additional blood glucose measurements are initially recommended when Bricanyl therapy is commenced in diabetic patients.

Potentially serious hypokalaemia may result from $beta_2$-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 (See Section 4.5). 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 $beta_2$-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 $beta_2$-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*).

There are some data which indicate that there is a risk of interaction between monoamine oxidase inhibitors, tricyclic antidepressants and terbuatline.

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 $beta_2$-agonist treatment.

4.7 Effects on ability to drive and use machines

None.

4.8 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. Most of the adverse reactions are characteristic of sympathomimetic amines. The majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment.

Frequency Classification	**Adverse Drug Reaction**	
	System Organ Class (SOC)	**Preferred term (PT)**
Very Common ≥1/10	Nervous System Disorders	Tremor Headache
Common <1/10 and ≥1/100	Cardiac Disorders	Tachycardia Palpitations
	Musculoskeletal and Connective Tissue Disorders	Muscle spasms
	Metabolism and Nutrition Disorders	Hypokalaemia
Unknown*	Cardiac Disorders	Arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles Myocardial ischaemia
	Gastrointestinal Disorders	Nausea
	Psychiatric Disorders	Sleep disoreder and Behavioural disturbances, such as agitation and restlessness
	Nervous System Disorders	Psychomotor hyperactivity
	Respiratory, Thoracic and Mediastinal Disorders	Bronchospasm**
	Skin and Subcutaneous Tissue Disorders	Urticaria Rash

* Reported spontaneously in post-marketing data and therefore frequency regarded as unknown
** Drugs for inhalation may through unspecified mechanisms cause bronchospasm.

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 beta$_2$-agonist, terbutaline,
ATC code: R03A C03.

Terbutaline sulphate is an adrenergic agonist which predominantly stimulates beta$_2$-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.

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 inhaler 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

IMED Healthcare Ltd
New Road
Buncrana
Co. Donegal

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/32/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th March 2010

10 DATE OF REVISION OF THE TEXT

October 2012