SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

BRONCHOPED (SYRUP)

COMPOSITION:

Each 5 ml contains:

Each 5 ml contains:

Terbutaline sulphate	1, 25 mg
Ammonium chloride	60 mg
Sodium citrate	25 mg

Preservative:

Sodium benzoate	0, 2 % m/v

Sugar free.

List of excipients: Sodium saccharin, Sodium cyclamate, Flavour Aniseed, Glycerine, Colour Grape, Colour Egg Yellow, Citric acid anhydrous, Hydroxpropylmethylcellulose (Methocel), Purified water

PHARMACOLOGICAL CLASSIFICATION:

A.10.1 Antitussives and expectorants.

PHARMACOLOGICAL ACTION:

Expectorant cough mixture with a selective bronchodilatory action.

INDICATIONS:

Symptomatic relief of cough associated with bronchospasm in children..

CONTRAINDICATIONS:

Hepatic and renal disease.

Hypersensitivity to any of the active ingredients.

Patients already on any other asthma medicine

WARNINGS AND SPECIAL PRECAUTIONS:

If there is no improvement within twelve to twenty four hours, a doctor must be consulted immediately.

BRONCHOPED should be used with caution when an increased susceptibility to sympathomimetic amines can be expected, for instance, in patients with hyperthyroidism, diabetes mellitus, ischaemic heart disease, arrhythmia or tachycardia and hypertension.

Beta$_2$-stimulants have an arrhythmogenic potential which must be considered in the treatment of the individual patient. Cardiac toxicity may occur, including ventricular arrythmias and possible fatalities, if used without due care or in overdose.

INTERACTIONS:

Non-selective β-blocking agents may partially or totally inhibit the effect of β-stimulants, and may therefore worsen the asthma or bronchospasm.

Beta-stimulants should not be given to patients receiving monamine oxidase inhibitors or within fourteen days of the termination thereof.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Children 3 - 6 years : 2, 5 ml – 5 ml three times daily.

7 years and older : 5 ml – 10 ml three times daily.

Do not exceed the prescribed dosage.

SIDE EFFECTS:

Gastrointestinal disorders:

- gastric irritation
- nausea and vomiting

Psychiatric disorders:

- nervousness

Musculoskeletal disorders:

- muscle tremor

Nervous system disorders:

- headache

Cardiac disorders:

- tachycardia
- palpitations

Vascular disorders:

- fainting

General disorders and administration site conditions:

- flushing
- hypokalaemia

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Large doses of ammonium chloride will cause gastric irritation, profound acidosis and hypokalaemia. Large doses of terbutaline will cause headache, anxiety, tremor, muscle cramp, palpitations and arrhythmias. A fall in blood pressure sometimes occurs.

In cases of overdose, treatment is symptomatic and supportive. Gastric lavage may be used. A $beta_2$-antagonist may be given to reduce the effects of terbutaline, but should be administered with care and may not be given to asthmatics.

IDENTIFICATION:

Dark brown clear syrup with an aniseed odour.

PRESENTATION:

Amber glass bottles of 100 ml and 200 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a well-sealed container. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

28/10.1/0206

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