Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dimotane Co. Paediatric Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of liquid contains:

Brompheniramine Maleate	2.0	mg
Pseudoephedrine Hydrochloride	15.0	mg
Codeine Phosphate (as hemihydrate)	3.0	mg

Excipients:

Sorbitol (E420)	1187.2	mg
Ethanol	95.6	mg
Amaranth (E123)	0.13	mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
A clear, dark pink solution with the odour of raspberry.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of cough associated with colds and other similar conditions for the upper respiratory tract.

4.2 Posology and method of administration

Taken orally.

Children:
6 - 12 years: 1 x 10 – 15 ml measure 3 times daily.
4 - 6 years: 1 x 10 ml measure 3 times daily.
2 - 4 years: 1 x 5 ml measures 3 times daily.
Under 2 years: Not to be used.

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.

Use in patients, especially children with glaucoma, urinary retention, high blood pressure, diabetes or thyroid disease.

Use in patients who are currently receiving other sympathomimetic drugs.

Use in patients who are receiving or have received within 14 days tricyclic anti-depressants or monoamine oxidase inhibitors.

4.4 Special warnings and precautions for use

This product may cause drowsiness and patients receiving it should not drive or operate machinery unless it has been shown that their physical and mental capacity remains unaffected.

This product may potentiate the effects of alcohol and other central nervous system depressants.

This product may act as a cerebral stimulant in children and occasionally in adults giving rise to insomnia, nervousness, hyperpyrexia, tremors and epileptiform convulsions.

Children on therapy should not be left unattended.

If the patient is receiving medication or is under a doctor's care, consult the doctor before using.

Do not exceed the stated dose.

Use with caution in patients with persistent or chronic cough such as occurs with smoking, asthma or emphysema or if cough is accompanied by phlegm.

If symptoms persist or worsen consult your doctor.

The physician or pharmacist should reassure himself that sympathomimetic containing preparations are not simultaneously administered by several routes e.g. orally and topically.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of anti-cholinergics e.g. some psychotropic drugs and atropine, may be potentiated by this product giving rise to tachycardia, mouth dryness, gastrointestinal disturbances, e.g. colic, urinary retention and headache.

This product should be used with caution in patients receiving digitalis, beta-adrenergic blockers, guanethidine, reserpine, methyldopa or other anti-hypertensive agents.

This product may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics anxiolytic sedatives and antipsychotics.

4.6 Pregnancy and lactation

This product should not be used during pregnancy unless considered essential by the physician. Breast feeding should be avoided.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness and patients receiving it should not drive or operate machinery unless it has shown that their physical and mental capacity remains unaffected.

4.8 Undesirable effects

In common with many antihistamines, Brompheniramine has an atropine-like action and therefore should be used with caution in patients with bronchial asthma, especially children.

Tolerance, psychological and physical dependence and constipation may occur.
May act as cerebral stimulant in children and occasionally in adults. If this occurs it is possible that tachycardia, anxiety, insomnia, nervousness, hyperpyrexia or tremor may occur and very rarely epileptiform convulsions. Therefore, children taking this product should not be left unattended for long periods.

4.9 Overdose

In severe overdosage with antihistamines the stomach should be emptied by aspiration and lavage. Other treatment is supportive and symptomatic and may include artificial respiration and external cooling for hyperpyrexia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Brompheniramine Maleate

Brompheniramine is an alkylamine derivative with the actions and uses of the Histamine H_1 receptor antagonists, including antimuscarinic and central sedative properties.

Pseudoephedrine Hydrochloride

Pseudoephedrine is a stereoisomer of ephedrine and has a similar action but has been stated to have less pressor activity and central nervous effects.

It is a sympathomimetic agent with indirect and direct effects on adrenergic receptors. It has alpha and beta-adrenergic activity and has pronounced stimulating effects on the central nervous system. In therapeutic doses it raises the blood pressure by increasing cardiac output and also by inducing peripheral vasoconstriction.

Codeine Phosphate

Codeine is an opium alkaloid with the activity similar to but weaker than that of morphine. It is given mainly by mouth in the treatment of mild to moderate pain and as an antitussive.

5.2 Pharmacokinetic properties

Brompheniramine Maleate

After oral administration Brompheniramine maleate appears to be well absorbed from the gastrointestinal tract. Peak plasma concentrations are achieved within about five hours. The elimination half-life is about 25 hours and the metabolites are primarily excreted in the urine.

Pseudoephedrine Hydrochloride

Pseudoephedrine is absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is excreted largely unchanged in the urine together with small amounts of its hepatic metabolite. It has a half-life of several hours; elimination is enhanced and the half-life is accordingly shorter in acidic urine.

Codeine Phosphate

Codeine and its salts are absorbed from the gastrointestinal tract. Ingestion of codeine phosphate produces peak plasma concentrations in about one hour. Codeine is metabolised by O- and N- demethylation in the liver to morphine, norcodeine and other metabolites including normorphine and hydrocodone. Codeine and its metabolites are excreted almost entirely by the kidney, mainly as a conjugate with glucuronic acid. The plasma half-life has been reported to be between three and four hours following administration by mouth or intramuscular injection.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate
Sodium Benzoate
Levomenthol
Amaranth (E123)
Caramel (E150)
Anhydrous Citric Acid
Liquid Sorbitol (non-crystallising) (E420)
Ethanol (96 %)
Glycerol
Cherry/Grenadine Flavour
Xanthan Gum
Sodium Cyclamate
Acesulfame Potassium
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type III Amber glass bottle filled up to 100 ml.

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 MARKETING AUTHORISATION HOLDER

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