PACKAGE INSERT

SCHEDULING STATUS
S2

PROPRIETARY NAME (and dosage form)
BENNETTS COLIC MIXTURE (syrup)

COMPOSITION
Each 5 ml of syrup contains:

Diphenhydramine HCl	3.125 mg
Belladonna Tincture	0.125 ml
Alcohol	4.7 % v/v
Preservatives:	
Methyl paraben	0.1 % m/v
Propyl paraben	0.01 % m/v

PHARMACOLOGICAL CLASSIFICATION
A.11.2 Gastro-intestinal anti-spasmodics and cholinolytics (anti-cholinergics)

PHARMACOLOGICAL ACTION
BENNETTS COLIC MIXTURE contains diphenhydramine HCl and belladonna, which both have anti-cholinergic activity.
Diphenhydramine HCl is a sedative antihistamine with antimuscarinic and prominent sedative properties.

INDICATIONS
BENNETTS COLIC MIXTURE is indicated in uncomplicated gastro-intestinal colic and spasms in babies one to four months old, where organic causes have been excluded. Safety and efficacy has not been demonstrated beyond two weeks.

CONTRA-INDICATIONS
BENNETTS COLIC MIXTURE is contra-indicated in patients with a hypersensitivity to either diphenhydramine or belladonna.

BENNETTS COLIC MIXTURE is also contra-indicated in the following conditions:
- angle-closure glaucoma
- a narrow angle between the iris and cornea, since it may raise intra-ocular pressure
- babies with fever
- conditions characterised by tachycardia, such as thyrotoxicosis, heart failure and cardiac surgery
- hypertension
- premature infants
- hepatic or renal failure

- suspected bowel obstruction

WARNINGS AND SPECIAL PRECAUTIONS

Belladonna may cause reduced bronchial secretion associated with the formation of mucous plugs. Children with Down's syndrome appear to have an increased susceptibility to some of the actions of belladonna, whereas those with albinism may have reduced susceptibility. Diphenhydramine may cause paradoxical hyperexcitability, nervousness, irritability and insomnia.
Do not give to children who have breathing problems such as chronic bronchitis, or who have glaucoma, without first consulting the doctor. May cause drowsiness. Do not give to children who are taking sedatives and tranquilizers, without first consulting the doctor, as sedatives and tranquilizers may increase the drowsiness.

Caution should be used when the following medical conditions exist: severe cardiovascular disorders, epilepsy and during an acute attack of asthma.
Safety and efficacy in infants weighing less than 3 kg has not been established.

DOSAGE AND DIRECTIONS FOR USE

The recommended dosage is 2.5 to 5 ml, to be taken 5 to 10 minutes before feeds, repeated if necessary after feeds. If the baby's weight is known: 1 ml/kg body weight, up to a maximum of 8 ml per dosage, and not more than 5 dosages per 24 hours. One half of the individualised dose can be administered 5 to 10 minutes before feeds and the remainder of the dose after the feed. Do not administer more frequently than 4 hourly.

SIDE-EFFECTS

The most common side-effect is central nervous system depression, with effects varying from slight drowsiness to deep sleep, although paradoxical stimulation may occasionally occur, especially in children. Other side-effects include headache and antimuscarinic effects such as dry mouth, thirst, thickened respiratory-tract secretions, cough, increased sweating, blurred vision, mydriasis, cycloplegia, photophobia, flushing and dryness of the skin, urinary difficulty or retention, constipation and increased gastric reflux. Occasional gastro-intestinal side-effects include nausea, vomiting, diarrhoea or epigastric pain. Palpitations and arrhythmias have been reported. Blood disorders, including agranulocytosis, leucopenia, haemolytic anaemia and thrombocytopenia occur rarely. Other side-effects that have been reported include convulsions, sweating, paraesthesia, extrapyramidal effects, tremor, sleep disturbances, fatigue, tremors, diplopia, nervousness, tingling and weakness of the hands, irritability, nightmares, hallucinations, tinnitus, hypotension, allergic dermatitis, drug fever, photosensitization, jaundice and hair loss.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Peripheral effects and other symptoms such as hyperthermia, hypertension, increased respiratory rate, nausea, vomiting, rash on the upper face and trunk, restlessness, excitement, ataxia, tremors, athetosis, hallucination and delirium and

occasionally seizures may occur. Fixed dilated pupils with a flushed face, sinus tachycardia, dyspnoea, urinary retention, dry mouth and fever may occur. In severe intoxication central nervous system depression, coma, circulatory and respiratory failure and death.
Central excitatory effects constitute the greatest danger, particularly in children who are more likely to exhibit central nervous system stimulation.
The stomach should be emptied by emesis or lavage. Treatment is symptomatic and supportive.

IDENTIFICATION
A red syrup with a distinct raspberry flavour.

PRESENTATION
BENNETTS COLIC MIXTURE is packed in a 50 ml or 100 ml round amber glass bottle, with a white screw-on cap.

STORAGE INSTRUCTIONS
Store at or below 25 ºC. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
W/11.2/0130

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Bennetts The Chemists (Pty) Ltd
16 Galaxy Avenue
Linbro Business Park
Linbro Park
Johannesburg
2065

DATE OF PUBLICATION OF THIS PACKAGE INSERT
2 April 2004