SCHEDULING STATUS: **S0**

PROPRIETARY NAME (AND DOSAGE FORM):

TELAMENT® PAEDIATRIC COLIC DROPS (DROPS)

COMPOSITION:

Each 1 ml contains:

Dimethicone 50 mg in a flavoured inert base

Preservatives:

Methylhydroxybenzoate 0,067 % m/v

Propylhydroxybenzoate 0,033 % m/v

Benzyl alcohol 0,5 % m/v

Sugar free

PHARMACOLOGICAL CLASSIFICATION:

A 11.10 Drugs acting on gastrointestinal tract - special combinations

PHARMACOLOGICAL ACTION:

Dimethicone decreases surface tension of the frothy contents of the gastrointestinal tract, breaks up the froth and allows small gas bubbles to coalesce. These larger bubbles easily rise to the surface and the liberated gas can readily be expelled, without regurgitation of food and with relief of the bloating and discomfort.

INDICATIONS:

Flatulence, dyspepsia and the relief of symptoms caused by excessive accumulation of gas in the gastrointestinal tract.

Gripes and colic in infants and children. Prevention and relief of post-operative gas accumulation in children.

DOSAGE AND DIRECTIONS FOR USE:

Infants and small children:	Eight to twelve drops with the feeds, or in water or any liquid, when required.
Children:	Half a medicine measureful (2,5 ml) when required.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Hypersensitivity reactions occur with the hydroxybenzoates. Generally these are of the delayed type, appearing as contact dermatitis. Rare occurrences of immediate reactions with urticaria and bronchospasm have been reported.

IDENTIFICATION:

TELAMENT PAEDIATRIC COLIC DROPS is white, banana flavoured and mildly viscous.

PRESENTATION:

Dropper bottles of 30 ml

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

E859 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Tiger Consumer Brands
2 Purlin Street
Isando
Kempton park
1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

17 November 2003

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM (EN DOSEERVORM):

TELAMENT® PAEDIATRIC COLIC DROPS (DRUPPELS)

SAMESTELLING:

Elke 1 ml bevat:

Dimetikoon 50 mg in 'n gegeurde onaktiewe basis

Preserveermiddels:

Metielhidroksibensoaat 0,067 % m/v

Propielhidroksibensoaat 0,033 % m/v

Bensielalkohol 0,5 % m/v

Suikervry

FARMAKOLOGIESE KLASSIFIKASIE:

A 11.10 Middels met uitwerking op maagdermkanaal - spesiale samestellings

FARMAKOLOGIESE WERKING:

Dimetikoon verminder die oppervlaktespanning van die skuimerige inhoud van die maagdermkanaal, breek die skuim op en maak dus samesmelting van die klein gasborreltjies moontlik. Die groter borrels styg maklik na die oppervlakte en die vrygestelde gas word geredelik uitgedryf, sonder terugvloei van die voedsel, en dit gaan gepaard met die verligting van buikswelling en ongemak.

INDIKASIES:

Winderigheid, dispepsie en die verligting van simptome wat deur oormatige gasophoping in die maagdermkanaal veroorsaak word.

Maagkrampe en koliek by babas en kinders. Voorkoming en verligting van gasophoping in kinders, na operasies.

DOSIS EN GEBRUIKSAANWYSINGS:

Babas en klein kinders: Agt tot twaalf druppels saam met voedings, of in water of 'n geskikte vloeistof, indien nodig.

Kinders:	'n Halwe medisynemaatvol (2,5 ml) indien nodig.

NEWE-EFFEKTE EN SPESIAL VOORSORGMAATREËLS:

Hipersensitiwiteitsreaksies kom voor met die hidroksibensoate. Oor die algemeen vind hierdie reaksies nie onmiddellik plaas nie en kom voor as kontakdermatitis.

Seldsame voorvalle van onmiddellike reaksies met urtikaria en brongospasma is aangemeld.

IDENTIFIKASIE:

TELAMENT PAEDIATRIC COLIC DROPS is wit, matig klewerig en het 'n piesanggeur.

AANBIEDING:

Drupperbottels met 30 ml.

BERGINGSAAMWYSING:

Bêre teen of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:

E859 (Wet 101/1965)

NAAM EN BESIGHEIDADRES VAN DIE APPLIKANT:

Tiger Consumer Brands
2 Purlin Straat
Isando
Kempton Park
1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

17 November 2003

FACSIMILE OF LABEL/ETIKETKONSEP

TELAMENT PAEDIATRIC COLIC DROPS

Vir koliek en winde by babas
For infant colic and wind

30 ml

Elke ml bevat / Each ml contains:

Dimethicone	50 mg	Dimetikoon
Preservatives:		Preserveermiddels:
Methyl hydroxybenzoate	0,067 % m/v	Metielhidroksibensoaat
Propyl hydroxybenzoate	0,033 % m/v	Propielhidroksiebensoaat
Benzyl alcohol	0,5 % m/v	Bensielalkohol

DOSAGE: Infants and small children: 8 to 12 drops with feeds.
Children: ½ medicine measureful (2,5 ml)
DOSIS: Babas en klein kinders: 8 tot 12 druppels saam met voedings.
Kinders: ½ medisynemaatvol (2,5 ml)

Shake the bottle before use. Store below 25 °C
KEEP OUT OF REACH OF CHILDREN
Skud die bottel voor gebruik. Bêre benede 25 °C
HOU BUITE BEREIK VAN KINDERS

Batch / Lot:
Expires / Verval:

Adcock Ingram Limited
www.adcock.co.za
Ref. No/ Verwnr.: E859 (Act/Wet 101/1965)