**PATIENT INFORMATION LEAFLET**

# TELAMENT® PAEDIATRIC COLIC DROPS (DROPS)

Simethicone 50mg/1ml

Saccharin Sodium as sweetener 0.2% m/v

Preservatives: Methyl hydroxybenzoate 0.067 % m/v;

Propyl hydroxybenzoate 0.033 % m/v;

Benzyl alcohol 0.5 % m/v

Sugar Free

**SCHEDULING STATUS:** **S0**

**PROPRIETARY NAME AND DOSAGE FORM:**

## TELAMENT® PAEDIATRIC COLIC DROPS (DROPS)

**Read this leaflet carefully, before giving TELAMENT PAEDIATRIC COLIC DROPS to your child, because it contains important information.**

TELAMENT PAEDIATRIC COLIC DROPS is available without a doctor's prescription, to treat mild illness. Nevertheless, you still need to use TELAMENT PAEDIATRIC COLIC DROPS carefully to get the best results.

Keep this leaflet. You may need to read it again.

Do not share TELAMENT PAEDIATRIC COLIC DROPS with any other person.

Ask your healthcare provider or pharmacist if you need more information or advice.

You must see a doctor if symptoms worsen or do not improve after 10 days.

**1.WHAT TELAMENT PAEDIATRIC COLIC DROPS IS USED FOR:**

TELAMENT PAEDIATRIC COLIC DROPS is a special combination medicine that acts on the gastrointestinal tract.

TELAMENT PAEDIATRIC COLIC DROPS is used for flatulence, dyspepsia and the relief of symptoms caused by excessive accumulation of gas in the gastrointestinal tract.

TELAMENT PAEDIATRIC COLIC DROPS is also used for gripes and colic in infants and children.

TELAMENT PAEDIATRIC COLIC DROPS is used for the prevention and relief of post-operative gas accumulation in children.

**2.BEFORE TAKING TELAMENT PAEDIATRIC COLIC DROPS:**

**Do not take TELAMENT PAEDIATRIC COLIC DROPS:**

If your child is hypersensitive (allergic) to TELAMENT PAEDIATRIC COLIC DROPS or any of the ingredients of TELAMENT PAEDIATRIC COLIC DROPS.

If your child is prone to hypersensitivity reactions with hydroxybenzoates (allergies to some preservatives).

If your child has severe liver function problems.

**WARNINGS AND PRECAUTIONS:**

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

**Special caution should be taken with TELAMENT PAEDIATRIC COLIC DROPS:**

If your child's discomfort persists or gets worse after taking TELAMENT PAEDIATRIC COLIC DROPS at the recommended dose.

**Using other medicines with TELAMENT PAEDIATRIC COLIC DROPS:**

If your child is prescribed other medicines, tell your healthcare professional before administering TELAMENT PAEDIATRIC COLIC DROPS to your child.

**Pregnancy and Breast-Feeding:**

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider before taking this medicine.

**3.HOW TO TAKE TELAMENT PAEDIATRIC COLIC DROPS:**

Always take TELAMENT PAEDIATRIC COLIC DROPS as directed. You should check with your healthcare professional if you are unsure.

**DO NOT EXCEED THE RECOMMENDED DOSE.**

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| **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. |

Do not share medicines prescribed for your child with others.

Shake well before use.

**If more TELAMENT PAEDIATRIC COLIC DROPS is taken than recommended (overdose):**

**In the event of an overdose, consult your doctor or pharmacist. If neither is available, Contact the nearest hospital or poison control centre.**

If a dose is forgotten, do not give a double dose to make up for the forgotten individual doses.

**4.POSSIBLE SIDE EFFECTS:**

If any of the following happens, stop taking / using TELAMENT PAEDIATRIC COLIC DROPS and tell you doctor immediately or go to the casualty department at your nearest hospital.

Skin rash or itching

Swelling of hands, feet, face, lips mouth or throat.

Difficulty breathing or swallowing

These are all serious side effects, if your child experiences any of them it is an allergic reaction to TELAMENT PAEDIATRIC COLIC DROPS. Your child may need urgent medical attention or hospitalisation.

If you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA online: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of TELAMENT PAEDIATRIC COLIC DROPS.

**5.STORAGE AND DISPOSAL OF TELAMENT PAEDIATRIC COLIC DROPS:**

Store at or below 25 °C in a cool, dry place and protect from light.

Keep medicines tightly closed.

Store TELAMENT PAEDIATRIC COLIC DROPS in the original container.

Do not use after the expiry date stated on the container.

Return all unused or expired medicine to your pharmacist.

Do not dispose of any medication in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

**6.WHAT TELAMENT PAEDIATRIC COLIC DROPS CONTAINS:**

Each 1 ml contains 50mg of Simethicone, as the active ingredient.

Preservatives: Methylhydroxybenzoate 0,067 % m/v

Propylhydroxybenzoate 0,033 % m/v

Benzyl alcohol 0,5 % m/v

Other Ingredients: Saccharin sodium, Propylene glycol, Xanthan gum, , Avicel, Purified Water, Glycerol, Flavouring.

**WHAT TELAMENT PAEDIATRIC COLIC DROPS LOOKS LIKE AND CONTENTS OF THE PACK:**

TELAMENT PAEDIATRIC COLIC DROPS is white, banana flavoured and mildly viscous in 30ml dropper bottles.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Tiger Consumer Brands
2 Purlin Street
Isando
Kempton park
1600

**REFERENCE NUMBER:**

E859 (Act 101/1965)
Zimbabwe: 94/16/2837

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

Date of the most recent amendment to the patient information leaflet as approved by Medicines Regulatory Authority:

**SKEDULERINGSTATUS:** **S0**

**EIENDOMSNAAM (EN DOSEERVORM):**

**TELAMENT® PAEDIATRIC COLIC DROPS (DRUPPELS)**

**SAMESTELLING:**

Elke 1 ml bevat:

Simetikoon 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:**

Simetikoon 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:**

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|---|---|
| **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