

**PEDIACARE GAS RELIEF DROPS DYE FREE- simethicone emulsion and simethicone liquid
Medtech Products Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

PediaCare Gas Relief Drops Dye Free

Drug Facts

Active ingredient

(in each 0.3 mL)

Simethicone Emulsion USP 66.7mg/Simethicone 20 mg

Purpose

Anti-Gas

Uses

relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

Warnings

When using this product

do not exceed 12 doses per day

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- **shake well before using**
- all dosages may be repeated as needed, after meals and at bedtime
- fill enclosed dropper to recommended dosage level

Dose by weight or if weight information is not available, dose by age.

- dispense liquid slowly into baby's mouth, toward inner cheek
- may mix with 1 oz. of cool water, infant formula or other suitable liquids
- clean dropper after each use and replace original cap

| age (yr) | weight (lb) | dose |
|---------------------|--------------------|-------------|
| infants under 2 | under 24 | 0.3 mL |
| children 2 and over | 24 and over | 0.6 mL |

Other information

- Do not freeze

- Store at room temperature 20-25°C (68-77°F)
- See bottle or box for lot number and expiration date

Inactive ingredients

citric acid, flavor, microcrystalline cellulose, propylene glycol, sodium benzoate, sodium carboxymethylcellulose, sucralose, xanthan gum

Questions or comments?

call **1-888-474-3099** Mon. – Fri. 8 am to 8 pm EST or visit us at **PediaCare.com**

PRINCIPAL DISPLAY PANEL

INFANTS 0-36 months

PediaCare® we care for kids™

Gas Relief DROPS

SIMETHICONE-ANTI GAS

NON-STAINING

1 FL OZ (30 mL)



PEDIACARE GAS RELIEF DROPS DYE FREE

simethicone emulsion and simethicone liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63029-811 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4) | SILICON DIOXIDE | 0.011 g in 1 mL |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 0.211 g in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:63029-811-01 | 1 in 1 BOX | | |
| 1 | | 30 mL in 1 BOTTLE, DROPPER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part332 | 08/01/2011 | |

Labeler - Medtech Products Inc. (122715688)

Revised: 4/2012

Medtech Products Inc.