## 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.

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## **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<sup>TM</sup>
Gas Relief DROPS
SIMETHICONE-ANTI GAS
NON-STAINING
1 FL OZ (30 mL)



TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OF MISSING.

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## INFANTS 0-36 months



## **Gas Relief** DROPS

SIMETHICONE-ANTI GAS

Safe enough to use at every feeding\*

#### **NON-STAINING**

No Alcohol No Saccharin No Artificial Colors No Artificial Flavors

**UP TO 100 DOSES** 

1 FL OZ (30 mL)

# Gas Relief

SIMETHICONE-ANTI GAS

PediaCare® medicines are specially developed for kids and provide safe and effective relief for your infant's fever, minor aches and pains or gas discomfort.

Visit us at www.PediaCare.com and use our symptom checker to select the right product for your child's symptoms. Also, check out our sick day activities and useful tips and information about childhood illness.

### PediaCare.\* we care for kids.

KEEP THIS BOX FOR COMPLETE INSTRUCTIONS.



## PEDIACARE GAS RELIEF DROPS DYE FREE

simethicone emulsion and simethicone liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63029-811

ORAL Route of Administration

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) (SILICON DIO XIDE - UNII:ETJ7Z6 XBU4)	SILICON DIOXIDE	0.011 g in 1 mL
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICO NE - UNII:92RU3N3Y1O)	DIMETHICONE	0.211 g in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
CELLULO SE, MICRO CRYSTALLINE (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			

P	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.