GAS RELIEF DROPS- dimethicone liquid Arymar 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.

Gas Relief Drops

Drug Facts

Active ingredient (in each 0.3mL)

Simethicone 20mg

Purpose

Antigas

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 this and all drugs out of the reach of children

In case pf overdose get medical help or contact a poison control center right away.

Directions

- shake well before using.
- all dosages may be repeated as needed, after meals and at bedtime.
- fill enclosed dropper to recommended dosage level.
- dispense liquid slowly into baby's mouth, toward the 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	0.3mL
children 2 and over	over 24	0.6 mL

Other information

Store between 15°-30°C (59°-86° F). Avoid exposing bottle to excessive heat and direct sunlight. Do not accept if safety seal is broken or missing. Keep box for information.

Inactive ingredients

Anise oil, carbomer, glycerin, methylparaben, propylparaben, purified water, sodium citrate and sucralose.

Questions or Comments?

Distributed by: **Arymar Inc.** 8004 NW 154 St. # 343 Miami Lakes FL 33016

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

 $\text{Arymar}_{\text{\tiny \i\!R}}$

Gas Relief Drops

Simethicone - Anti-Gas

Safe enough to use every feeding

- No Alcohol No Saccharin
- No Artificial Colors
- No Artificial Flavors

1 Fl. Oz. (30 ml)

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GAS RELIEF DROPS

dimethicone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70570-0197
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	20 mg in 0.3 mL

Inactive Ingredients		
Ingredient Name	Strength	
Anise Oil (UNII: 6 Y89 129 C8 H)		
Carboxypolymethylene (UNII: 0 A5MM30 7FC)		
Glycerin (UNII: PDC6A3C0OX)		
Methylparaben (UNII: A2I8C7HI9T)		
Propylparaben (UNII: Z8IX2SC1OH)		
Water (UNII: 059QF0KO0R)		
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)		
Sucralose (UNII: 96K6UQ3ZD4)		

1	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70570- 0197-1	1 in 1 CARTON	02/01/2015	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	0 2/0 1/20 15	

Labeler - Arymar Inc. (021650273)

Revised: 3/2019 Arymar Inc.