

SHOPRITE INFANTS SIMETHICONE- simethicone emulsion
Wakefern Food Corporation

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.

ShopRite Infants' Simethicone Drops Drug Facts

Active ingredient (in each 0.3 mL)

Simethicone 20 mg

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 out of reach of children.

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	0.3 mL
children over 2	over 24	0.6 mL

Other information

store at room temperature (59°-86°F)

Inactive ingredients

citric acid, flavor, hypromellose, maltitol, methylcellulose, mono- and di- glycerides, polyethylene glycol, polyethylene glycol stearate, polysorbate 65, purified water, sodium benzoate, sodium citrate, sorbic acid, xanthan gum

Questions or comments?

1-800-SHOPRITE

Principal Display Panel

Compare to: Active Ingredient in Infants' Mylicon® Drops

Infants'

SIMETHICONE DROPS

SIMETHICONE 20 mg

ANTI-GAS

Gas Relief

Non-Staining

No Alcohol

No Saccharin

No Artificial Flavor

No Artificial Colors

Dosage Dropper Enclosed

1 FL OZ (30mL)



Infants'

ShopRite®

SIMETHICONE DROPS

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Infants'

ShopRite®

SIMETHICONE DROPS

SIMETHICONE 20 mg ANTI-GAS

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Dosage Dropper
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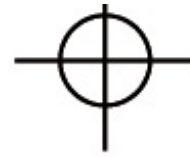
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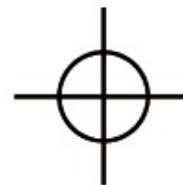
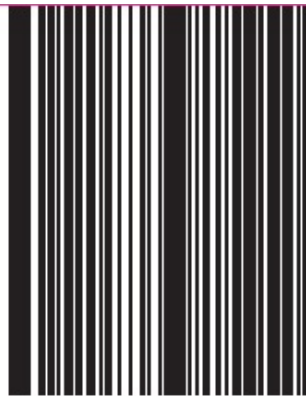
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LOT NO.

EXP.

: 88210 88 C1





Do not use if printed bottle wrap is broken or missing

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*This product is not manufactured or distributed by Johnson & Johnson • MERCK Consumer Pharmaceuticals Co., distributor of Infants' Mylicon® Drops.

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5000 RIVERSIDE DRIVE
KEASBEY, NJ 08832
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Your complete satisfaction or your money back.
We welcome your questions and comments.
Call: 1-800-ShopRite or
Email: www.shoprite.com





SHOPRITE INFANTS SIMETHICONE

simethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-882
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTITOL (UNII: D65DG142WK)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBIC ACID (UNII: X045WJ989B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 65 (UNII: 14BGY2Y3MJ)	

Product Characteristics

Color	WHITE (white to off white, opaque)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-882-10	1 in 1 CARTON	06/16/2013	

1	30 mL in 1 BOTTLE; 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	06/16/2013	

Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2018

Wakefern Food Corporation