

SIMETHICONE - simethicone solution/ drops

Physicians Total Care, 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.

Infants Simethicone Drops

Active ingredient (in each 0.3 mL)

Simethicone 20 mg

Purpose

Anti-gas

Uses

Relieves the discomfort of infant gas frequently caused by air swallowing or certain formulas or foods.

Warnings

Keep out of reach of children.

In case of 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 or as directed by a physician. Do not exceed 12 doses per day.
- fill enclosed dropper to recommended dosage level and dispense liquid slowly into baby's mouth, toward the inner cheek
- dosage can also be mixed with 1 oz of cool water, infant formula or other suitable liquids
- for best results, clean dropper after each use and replace original cap

Age	Weight	Dose
newborn	- - - -	0.3 mL
infants under 2 years	under 24 lbs	0.3 mL
children over 2 years	over 24 lbs	0.6 mL

Other information

- store at room temperature 15°- 30°C (59°- 86°F)
- do not freeze

You may report serious side effects to: 130 Vintage Drive, Huntsville, AL 35811.

Inactive ingredients

carbomer, citric acid, FD&C red #3, flavor, hypromellose, purified water, saccharin sodium, sodium

benzoate, sodium citrate

Made in the **USA**
for Qualitest Pharmaceuticals
Huntsville, AL 35811

Rev. 6/10 R6
8276455 0894

Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

PRINCIPAL DISPLAY PANEL



SIMETHICONE			
simethicone solution/ drops			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5620(NDC:0603-0894)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	63.3 mg in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)		SILICON DIOXIDE	3.7 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
WATER (UNII: 059QF0KO0R)			

SACCHARIN SODIUM (UNII: SB8ZUX40TY)					
SODIUM BENZOATE (UNII: OJ245FE5EU)					
SODIUM CITRATE (UNII: 1Q73Q2JULR)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54868-5620-0	1 in 1 CARTON			
1		30 mL in 1 BOTTLE			
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL		part332	10/30/2007		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 5/2012

Physicians Total Care, Inc.