

QUITA COLICOS GAS RELIEF DROPS- simethicone liquid
DLC Laboratories, 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.

QUITA CÓLICOS® GAS RELIEF DROPS

Drug Facts

Active ingredient (in each 0.3 mL)

Simethicone 20 mg

Purpose

Antigas

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**
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- **only use the enclosed dropper.** Fill dropper to the recommended dosage level and dispense liquid slowly into baby's mouth, toward the inner cheek.
- all dosages may be repeated as needed, after meals and at bedtime or as directed by a doctor
- do not exceed 12 doses per day
- dosage can also be mixed with 1 oz. of cool water, infant formula or other suitable liquids
- clean dropper well after each use and replace original cap

mL = milliliter

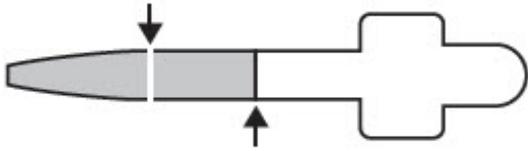
Other information

- **do not use if printed bottle wrap is missing or broken**
- store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredients

citric acid, hydroxypropyl methylcellulose, maltitol, natural flavor, purified water USP, sodium benzoate, sodium citrate, xanthan gum

INFANTS (under 2 years): 0.3 mL



CHILDREN (over 2 years): 0.6 mL

AGE (years)	WEIGHT (lbs.)	DOSE
INFANTS under 2	Under 24 lbs.	0.3 mL
CHILDREN over 2	More than 24 lbs.	0.6 mL

Questions

1-800-858-3889

Manufactured by:
De La Cruz Products
A Division of DLC Laboratories, Inc.
Paramount, CA 90723 USA

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box

De La Cruz®
Baby

Gas
Relief Drops

Gotas Quita Cólicos®

Simethicone
— ANTIGAS —

Safe for newborns & infants
No alcohol, No dyes, No saccharin

Up To 100 Doses

NATURAL
CHERRY FLAVOR

1 FL OZ (30 mL)



De la Cruz
Baby
Gas Relief
Drops
Gotas Quita Cólicos*

Safe
for newborns

Seguro para Recién Nacidos



Gas Relief
Drops
Gotas Quita Cólicos*

Simethicone / Simeicona

ANTIGAS

Safe for newborns & infants
No alcohol, No dyes, No saccharin
Seguro para recién nacidos y bebés
Sin alcohol, Sin colorantes, Sin sacarina

Up to 100 Doses
Hasta 100 dosis

NATURAL
CHERRY FLAVOR
SABOR A CEREZA

1 FL OZ (30 mL)

*Use only as directed /
Usar sólo según las indicaciones

Drug Facts (continued)

Other information

- do not use if printed bottle wrap is missing or broken
- store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredients
citric acid, hydroxypropyl methylcellulose, mannitol, natural flavor, purified water USP, sodium benzoate, sodium citrate, xanthan gum

INFANTS (under 2 years): 0.3 mL



CHILDREN (over 2 years): 0.6 mL

AGE (years)	WEIGHT (lbs.)	DOSE
INFANTS under 2	Under 24 lbs.	0.3 mL
CHILDREN over 2	More than 24 lbs.	0.6 mL

Retain carton for complete product information.

Manufactured by / Fabricado por:
De La Cruz Products
A Division of D.L.C. Laboratories, Inc.
Paramount, CA 90723 USA
Questions / Preguntas: 1-800-658-3889

dclabs.com
@dclaboratories

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Simethicone 20 mg	Antigas

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- do not exceed 12 doses per day
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- clean dropper well after each use and replace original cap

mL = milliliter

Datos Medicinales

Ingrediente activo (en cada 0.3 ml)	Propósito
Simeticona 20 mg	Antigas

Usos
Alivia la molestia de gases infantiles debido a la ingestión de aire o de ciertas fórmulas o alimentos.

Advertencias
Manténgase fuera del alcance de los niños. En caso de sobredosis, pida ayuda médica o comuníquese con un Centro de Control de Envenenamientos inmediatamente.

Instrucciones

- agítese bien antes de usar
- encuentre la dosis correcta en la tabla. Si es posible, use el peso para encontrar la dosis; de lo contrario, use la edad.
- use únicamente el gotero incluido. Llene el gotero al nivel de la dosis recomendada y administre el líquido lentamente dentro de la boca del bebé, hacia la mejilla interior.
- todas las dosis pueden ser repetidas según sea necesario, después de las comidas y al acostarse o según lo indicado por un médico.
- no exceda 12 dosis por día
- la dosis también puede ser mezclada con 1 oz. de agua fresca, fórmula para bebés u otro líquido apropiado
- limpie bien el gotero después de cada uso y cierre la botella con la tapa original

ml = mililitro

P0330-42R

Datos Medicinales (continuación)

Otra información

- no lo use si el sello impreso alrededor de la botella falta o está roto
- mantener guardado a temperatura ambiente
- no congelar
- ver la base de la caja para encontrar el número de lote y la fecha de vencimiento

Ingredientes inactivos
ácido cítrico, hidroxipropilmetilcelulosa, manitol, saborizante natural, agua purificada USP, benzoato de sodio, citrato de sodio, goma xantana

BEBÉS (menores de 2 años): 0.3 ml



NIÑOS (mayores de 2 años): 0.6 ml

Edad (años)	Peso (lb)	Dosis
Bebés menores de 2	Menos de 24 libras	0.3 ml
Niños mayores de 2	Más de 24 libras	0.6 ml

Conserve la caja para información completa sobre el producto.



LOT
EXP

3-24286-16240-6

QUITA COLICOS GAS RELIEF DROPS

simethicone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24286-1533
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTITOL (UNII: D65DG142WK)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24286-1533-8	1 in 1 BOX	03/18/2014	
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	03/18/2014	

Labeler - DLC Laboratories, Inc. (093351930)**Establishment**

Name	Address	ID/FEI	Business Operations
DLC Laboratories, Inc.		093351930	MANUFACTURE(24286-1533) , LABEL(24286-1533)

Revised: 7/2019

DLC Laboratories, Inc.