GAS AND COLIC KIDS RELIEF - colocynthis, magnesia phosphorica, chamomilla, dioscorea villosa liquid

HOMEOLAB USA INC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS

Active Ingredients HPUS:

Colocynthis (Bitter apple) 6X

Magnesia phosphorica (Magnesium hydrogen phosphate) 6X

Chamomilla (German chamomile) 6X

Dioscorea villosa (Wild yam) 6X

Purpose

Abdominal bloating, colic and nausea Abdominal cramps Nausea, agitation and irritability Intestinal gas, burping and colic-like pain

The letters 'HPUS' indicate that the components in this product are officially monographed in the Homoeopathic Pharmacopoeia of the United States.

*These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice.

RETAIN CARTON FOR COMPLETE INSTRUCTIONS

Uses

This homeopathic medicine is made from a combination of ingredients traditionally used to help relieve symptoms associated with colic*:

- intestinal gas
- abdominal pain
- bloating
- nausea
- burping

Warnings

Do not use if imprinted shrink seal neckband is broken or missing.

Stop use and ask a doctor in cases of high fever or if symptoms worsen or persist for more than 2 days.

Keep out of reach of children.

Directions

Children under 6 months of age: Consult a licensed healthcare practitioner before using this product.

Children 6 months to 2 years old: 0.5 ml orally every 8 hours or 3 times a day.

Children 2 to 9 years old: 0.75 ml orally every 8 hours or 3 times a day.

Other information

Store at room temperature.

Inactive Ingredients

Purified water, sorbitol, raspberry and grape flavor, sodium benzoate, potassium sorbate, citric acid.

CARTON



LABEL

Drug Facts (continued)

Warnings Do not use if imprinted shrink seal neckband is broken or missing.

Stop use and ask a doctor in cases of high fever or if symptoms worsen or persist for more than 2 days.

Keep out of reach of children.

Mfd for: HOMEOLAB USA 3025 de l'Assomption Blvd. Montreal QC Canada H1N 2H2 www.kidsrelief.com

Item no. 512-09083 Rev. 03/14



RETAIN CARTON FOR COMPLETE INSTRUCTIONS

Drug Facts

Active Ingredients HPUS

Colocynthis 6X, Magnesia phosphorica 6X, Chamomilla 6X, Dioscorea villosa 6X.

Directions = Children under 6 months

of age: Consult a licensed healthcare practitioner before using this product ■ Children 6 months to 2 years old: 0.5 ml orally every 8 hours or 3 times a day

■ Children 2 to 9 years old: 0.75ml orally every 8 hours or 3 times a day.

GAS AND COLIC KIDS RELIEF

colocynthis, magnesia phosphorica, chamomilla, dioscorea villosa liquid

Product Information

HUMAN OTC DRUG NDC:60512-9083 Product Type Item Code (Source)

ORAL Route of Administration

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS CITRULLUS COLOCYNTHIS 6 [hp_X] COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17) FRUIT PULP in 25 mL MAGNESIUM PHO SPHATE, DIBASIC TRIHYDRATE (UNII: HF539 G9 L3Q) MAGNESIUM PHOSPHATE, 6 [hp_X] DIBASIC TRIHYDRATE (MAGNESIUM CATION - UNII:T6 V3LHY838) in 25 mL MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA -6 [hp_X] MATRICARIA RECUTITA UNII:G0R4UBI2ZZ) in 25 mL DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8) (DIOSCOREA VILLOSA ROOT 6 [hp_X] DIOSCOREA VILLOSA ROOT - UNII:IWY3IWX2G8) in 25 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	RASPBERRY, GRAPE	Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60512-9083-8	1 in 1 CARTON		
1		25 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		08/22/2011		

Labeler - HOMEOLAB USA INC (202032533)

Establishment				
Name	Address	ID/FEI	Business Operations	
HOMEOLAB USA INC		202032533	manufacture(60512-9083)	

Revised: 4/2014 HOMEOLAB USA INC