GAS AND COLIC KIDS RELIEF BABY- 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 seal under bottle cap 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



GAS AND COLIC KIDS RELIEF BABY

colocynthis, magnesia phosphorica, chamomilla, dioscorea villosa liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60512-9200	
Route of Administration	ORAL			
1.0 4.0 01 1.4 1				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT PULP	6 [hp_X] in 25 mL

MAGNESIUM PHO SPHATE, DIBASIC TRIHYDRATE (UNII: HF539 G9 L3Q) (MAGNESIUM CATION - UNII:T6 V3LHY838)	MAGNESIUM PHO S PHATE, DIBASIC TRIHYDRATE	6 [hp_X] in 25 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_X] in 25 mL
DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8) (DIOSCOREA VILLOSA ROOT - UNII:IWY3IWX2G8)	DIOSCOREA VILLOSA ROOT	6 [hp_X] 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				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:60512-9200-8	1 in 1 BOX	08/16/2016		
1		25 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	
unapproved homeopathic		08/16/2016		

Labeler - HOMEOLAB USA INC (202032533)

Establishment				
Name	Address	ID/FEI	Business Operations	
HOMEOLAB USA INC		202032533	manufacture(60512-9200)	

Revised: 8/2016 HOMEOLAB USA INC