

**COLIC RELIEF- aloe, carbo vegetabilis, carum carvi, chamomilla, foeniculum vulgare, melissa officinale, mentha piperita, prunus spinosa, zingiber officinale liquid**

**CVS Pharmacy**

*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.*

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**Drug Facts:**

**ACTIVE INGREDIENTS:**

Aloe 5X, Carbo Vegetabilis 1X, Carum Carvi 5X, Chamomilla 5X, Foeniculum Vulgare 5X, Melissa Officinale 5X, Mentha Piperita 5X, Prunus Spinosa 5X, Zingiber Officinale 5X.

**USES:**

Temporarily relieves the symptoms of infant gas, colic, upset stomach, bloating, hiccups.

**WARNINGS:**

• **DO NOT USE IF OUTER IMPRINTED SAFETY SEAL ON GLASS BOTTLE OR PROTECTIVE WRAP ON ORAL DISPENSER ARE BROKEN OR MISSING.**

• **Stop use and consult a doctor if** symptoms last more than 7 days or inflammation, fever or infection occurs.

• As with all medications, it is important to ensure that your child's medical professional is aware of the use of this product.

• Because product is black, a temporarily, harmless, darkening of the stool may occur.

• May stain fabric; protect clothing and furniture.

**KEEP OUT OF REACH OF CHILDREN:**

**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 use to obtain uniform dark mixture.

• Remove outer imprinted safety seal from glass bottle and protective wrap on oral dispenser.

• When symptoms occur, fill enclosed oral dispenser up to indicated dose level and dispense liquid slowly, drop-by-drop into mouth, between cheek and gums.

• If needed, repeat every 30 minutes for up to 3 doses, or as directed by a physician. Do not exceed 4 full doses in 24 hours.

• Recap glass bottle and clean oral dispenser.

Weight	Dose
Under 20 lbs.	1/4 teaspoon (1.25 mL)
Over 20 lbs.	1/2 teaspoon (2.5 mL)

**OTHER SAFETY INFORMATION:**

Please note: Sleep may follow naturally after relief.

**STORE AT ROOM TEMPERATURE, OUT OF DIRECT SUNLIGHT.**

**INDICATIONS:**

Temporarily relieves the symptoms of infant gas, colic, upset stomach, bloating, hiccups.

**INACTIVE INGREDIENTS:**

Citric Acid, Glycerin, Potassium Benzoate, Potassium Citrate, Potassium Sorbate, Purified Water, Xylitol.

**QUESTIONS:**

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**PACKAGE LABEL DISPLAY:**

**CVS** NDC 59779-542-01  
Health

Safe & Fast-Acting

**Colic Relief**

**HOMEOPATHIC MEDICINE**

**ORAL SUSPENSION**

Great Tasting

- Relieves gas & Colic
- Soothes upset stomach
- No artificial flavors  
or colors

2 FL OZ (59 mL)

#### Active Ingredients

ALOE 5X, CARBO VEGETABILIS 1X, CARUM CARVI 5X, CHAMOMILLA 5X, FOENICULUM VULGARE 5X, MELISSA OFFICINALIS 5X, MENTHA PIPERITA 5X, PRUNUS SPINOSA 5X, ZINGIBER OFFICINALE 5X

#### Directions

- **SHAKE WELL** before use to obtain uniform dark mixture.
- Remove outer imprinted safety seal from glass bottle and protective wrap on oral dispenser.
- When symptoms occur, fill enclosed oral dispenser up to indicated dose level and dispense liquid **slowly, drop-by-drop**, into mouth, between cheek and gums.
- If needed, repeat every 60 minutes for up to 3 doses, or as directed by a physician. Do not exceed 4 full doses in 24 hours.
- Recap glass bottle and clean oral dispenser.

Weight	Dose
UNDER 20 lbs	1/4 teaspoon (1.25 mL)
OVER 20 lbs	1/2 teaspoon (2.5 mL)

**Please Note:** Sleep may follow naturally after relief.

**Uses:** Temporarily relieves the symptoms of infant gas, colic, upset stomach, bloating and hiccups.



NDC 59779-542-01

#### Warnings

- **DO NOT USE IF OUTER IMPRINTED SAFETY SEAL ON GLASS BOTTLE OR PROTECTIVE WRAP ON ORAL DISPENSER IS BROKEN OR MISSING.**
- **Stop use and consult a doctor** if symptoms last more than 7 days or inflammation, fever or infection occurs.
- As with all medications, it is important to ensure that your child's medical professional is aware of the use of this product.
- Because product is black, a temporary, harmless darkening of the stool may occur.
- May stain fabric; protect clothing and furniture.

#### KEEP OUT OF REACH OF CHILDREN.

In case of overdose, get medical help or contact a Poison Control Center right away.

**STORE AT ROOM TEMPERATURE, OUT OF DIRECT SUNLIGHT.**

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## Safe & Fast-Acting Colic Relief

### HOMEOPATHIC MEDICINE ORAL SUSPENSION

#### Great tasting

- Relieves gas & colic
- Soothes upset stomach
- No artificial flavors or colors

2 FL OZ (59 mL)

#### Drug Facts

Active ingredients	Purpose
Aloe 5X	gas relief, bloating
Carbo Vegetabilis 1X	gas relief, upset stomach
Carum Carvi 5X	digestive aid
Chamomilla 5X	irritability, hiccups
Foeniculum Vulgare 5X	gas relief
Melissa Officinalis 5X	irritability, restlessness
Mentha Piperita 5X	bloating, colic
Prunus Spinosa 5X	upset stomach, colic
Zingiber Officinale 5X	digestive aid

#### Uses

Temporarily relieves the symptoms of infant: gas, colic, upset stomach, bloating, hiccups.

#### Warnings

- **Do not use** if outer imprinted safety seal on glass bottle or protective wrap on oral dispenser is broken or missing.
- **Stop use and consult a doctor** if symptoms last more than 7 days or inflammation, fever or infection occurs.
- As with all medications, it is important to ensure that your child's medical professional is aware of the use of this product.
- Because product is black, a temporary, harmless darkening of the stool may occur.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### Directions

Weight	Dose
Under 20 lbs	1/4 teaspoon (1.25 mL)
Over 20 lbs	1/2 teaspoon (2.5 mL)

- Shake well before use to obtain uniform dark mixture. (continued)

#### Drug Facts (continued)

#### Directions (continued)

- Remove outer imprinted safety seal from glass bottle and protective wrap on oral dispenser.
- When symptoms occur, fill enclosed oral dispenser up to indicated dose level and dispense liquid **slowly, drop-by-drop**, into mouth, between cheek and gums.
- If needed, repeat every 60 minutes for up to 3 doses, or as directed by a physician. Do not exceed 4 full doses in 24 hours.
- Recap glass bottle and clean oral dispenser.

#### Other information

- Please note: Sleep may follow naturally after relief.
- Store at room temperature, out of direct sunlight.
- May stain fabric; protect clothing and furniture.

#### Inactive ingredients

citric acid, glycerin, potassium benzoate, potassium citrate, potassium sorbate, purified water, xylitol

#### Questions or comments?

Call (800) 746-7287  
Visit us at  
**CVS.com**  
Or ask your physician, health care practitioner or CVS Health™ pharmacist.



Compare to the active ingredients in Colic Calm™

NDC 59779-542-01

## Safe & Fast-Acting Colic Relief

### HOMEOPATHIC MEDICINE ORAL SUSPENSION

#### Great tasting

- Relieves gas & colic
- Soothes upset stomach
- No artificial flavors or colors



Actual Product Size on Side Panel

2 FL OZ (59 mL)

CVS Health™ Colic Relief safely and effectively relieves infant gas, colic, upset stomach, bloating and hiccups as well as irritability associated with these symptoms.

**RETAIN CARTON FOR COMPLETE INSTRUCTIONS**

Does not contain:  
Sugar, Sodium Bicarbonate (Baking Soda), Simethicone, Wheat, Gluten, Soy, Dairy, Animal Products, Artificial Flavors or Colors

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\*These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

#967969



## COLIC RELIEF

aloe, carbo vegetabilis, carum carvi, chamomilla, foeniculum vulgare, melissa officinale, mentha piperita, prunus spinosa, zingiber officinale liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-542
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALOE</b> (UNII: V5VD430 YW9) (ALOE - UNII:V5VD430 YW9)	ALOE	5 [hp_X] in 1 mL
<b>ACTIVATED CHARCOAL</b> (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	1 [hp_X] in 1 mL
<b>CARAWAY SEED</b> (UNII: W2FH8O2BBE) (CARAWAY SEED - UNII:W2FH8O2BBE)	CARAWAY SEED	5 [hp_X] in 1 mL
<b>MATRICARIA RECUTITA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	5 [hp_X] in 1 mL
<b>FENNEL SEED</b> (UNII: G3QC02NIE6) (FENNEL SEED - UNII:G3QC02NIE6)	FENNEL SEED	5 [hp_X] in 1 mL
<b>MELISSA OFFICINALIS</b> (UNII: YF70189L0N) (MELISSA OFFICINALIS - UNII:YF70189L0N)	MELISSA OFFICINALIS	5 [hp_X] in 1 mL
<b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)	MENTHA PIPERITA	5 [hp_X] in 1 mL
<b>PRUNUS SPINOSA FLOWER BUD</b> (UNII: 53Y84VPS2W) (PRUNUS SPINOSA FLOWER BUD - UNII:53Y84VPS2W)	PRUNUS SPINOSA FLOWER BUD	5 [hp_X] in 1 mL
<b>GINGER</b> (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	5 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POTASSIUM BENZOATE</b> (UNII: 763YQN2K7K)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-542-01	1 in 1 CARTON		
1		59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/10/2015	

Labeler - CVS Pharmacy (062312574)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(59779-542) , api manufacture(59779-542) , label(59779-542) , pack(59779-542)

Revised: 2/2016

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