

**COUGH AND COLD NIGHTTIME FORMULA KIDS RELIEF- drosera, arnica montana, bryonia, cetraria islandica, coccus cacti, corallium rubrum, stannum metallicum, chamomilla, coffea cruda syrup
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:

Drosera (Sundew) 1C

Arnica montana (Leopard`s bane) 3C

Bryonia (White bryony) 3C

Cetraria islandica (Iceland moss) 1C

Coccus cacti (Cochineal) 3C

Corallium rubrum (Red coral) 3C

Stannum metallicum (Tin) 3C

Chamomilla (German chamomile) 4C

Coffea cruda (Coffee) 4C

Purpose

Dry cough

Aches and pains, chest congestion

Painful cough, Fever

Cough with expectoration

Cough with expectoration

Painful cough

Mucus, cough and chills

Restlessness, irritability and nocturnal awakenings

Restlessness and sleeplessness

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.

Uses

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

- dry cough

- cough with expectoration
- chest congestion
- fever
- aches and pains

Warnings

Stop use and ask a doctor if • pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults) • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

Keep out of reach of children. In case of accidental overdose, contact a medical professional or poison control center immediately.

Directions

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

Children 6 months to 2 years old: 2.5 ml or 1/2 teaspoon every 8 hours or 3 times a day.

Children 2 to 12 years old: 5 ml or 1 teaspoon every 8 hours or 3 times a day.

Other information

- Store at room temperature.
- **Do not use** if seal under bottle cap is broken or missing.

Inactive ingredients

Purified water, sorbitol, caramel, sodium benzoate, potassium sorbate, citric acid.

CARTON



COUGH AND COLD NIGHTTIME FORMULA KIDS RELIEF

drosera, arnica montana, bryonia, cetraria islandica, coccus cacti, corallium rubrum, stannum metallicum, chamomilla, coffea cruda syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60512-9212
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DROSERA ROTUNDFOLIA FLOWERING TOP (UNII: 750014T1HG) (DROSERA ROTUNDFOLIA FLOWERING TOP - UNII:750014T1HG)	DROSERA ROTUNDFOLIA FLOWERING TOP	1 [hp_C] in 100 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	3 [hp_C] in 100 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	3 [hp_C] in 100 mL
CETRARIA ISLANDICA SUBSP. ISLANDICA (UNII: BJ7YPN79A1) (CETRARIA ISLANDICA SUBSP. ISLANDICA - UNII:BJ7YPN79A1)	CETRARIA ISLANDICA SUBSP. ISLANDICA	1 [hp_C] in 100 mL
PROTORTONIA CACTI (UNII: LZB7TFX1LT) (PROTORTONIA CACTI - UNII:LZB7TFX1LT)	PROTORTONIA CACTI	3 [hp_C] in 100 mL
CORALLIUM RUBRUM EXOSKELETON (UNII: 2CA71K0DLE) (CORALLIUM RUBRUM EXOSKELETON - UNII:2CA71K0DLE)	CORALLIUM RUBRUM EXOSKELETON	3 [hp_C] in 100 mL

TIN (UNII: 387GMG9FH5) (TIN - UNII:387GMG9FH5)	TIN	3 [hp_C] in 100 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	4 [hp_C] in 100 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	4 [hp_C] in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CARAMEL (UNII: T9D99G2B1R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60512-9212-5	1 in 1 CARTON	11/01/2016	
1		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:60512-9212-4	1 in 1 CARTON	11/01/2016	
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:60512-9212-9	1 in 1 CARTON	11/01/2016	
3		250 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		11/01/2016	

Labeler - HOMEOLAB USA INC (202032533)

Establishment

Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC		202032533	manufacture(60512-9212)

Revised: 4/2017

HOMEOLAB USA INC