COUGH AND COLD NIGHTTIME FORMULA KIDS RELIEF - drosera, arnica montana, bryonia, cetraria islandica, belladonna, coccus cacti, 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

Drosera (Sundew) 1C

Arnica montana (Leopard's bane) 3C

Bryonia (White bryony) 3C

Cetraria islandica (Iceland moss) 1C

Belladonna (Deadly nightshade) 3C

Coccus cacti (Cochineal) 3C

Stannum metallicum (Tin) 3C

Chamomilla (German chamomile) 4C

Coffea cruda (Coffee) 4C

The letters HPUS indicate that the components in this products are officially monographed in the Homeopathic Pharmacopoeia of the United States.

PURPOSE

Dry cough.

Aches and pains, chest congestion.

Painful cough.

Cough with expectoration.

Cold and fever.

Cough with expectoration.

Mucus, cough and chills.

Restlessness, irritability and nocturnal awakenings.

Restlessness and sleeplessness.

USES

This homeopathic medicine helps 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 in cases of high fever or if symptoms worsen or persist for more than 5 days.

Keep out of reach of children.

DIRECTIONS

Do not use more than directed.

Do not take with food.

Take before bedtime. Repeat every 8 hours, as needed. Reduce intake with improvement or as directed by a healthcare professional.

| Age | Dose |
|-----------------------------------|--------------|
| Children 6 years of age and older | 1 teaspoon |
| Children 2 to 5 years of age | 1/2 teaspoon |
| Children under 2 years of age | Ask a doctor |

OTHER INFORMATION

Store at room temperature.

Do not use if seal is broken or missing.

INACTIVE INGREDIENTS

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

CARTON

Drug Facts

| Active Ingredients HPUS: Purpose Drosera 1C | ose ough estion | |
|---|-----------------------|--|
| . – | ough | |
| (White bryony) Cetraria islandica 1C cough with expectoration | ation | |
| (Iceland moss) Belladonna 3Ccold and fever | fever | |
| (Deadly nightshade) Coccus cacti 3Ccough with expectoration | ation | |
| (Cochineal) Stannum metallicum 3Cmucus, cough and chills | chills | |
| (Tin) | 0000000 | |

The letters "HPUS" indicate that the components in this product are officially monographed in the Homœopathic Pharmacopoeia of the United States

Coffea cruda 4C restlessness and sleeplessness

(Coffee)

Chamomilla 4C...

(German chamomile)

... restlessness, irritability and nocturnal awakenings

Uses
This homeopathic medicine helps 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 in cases of high fever or if symptoms worsen or persist for more than

Keep out of reach of children.

PRODUCT OF CANADA Homeopathic Medicine

Drug Facts (continued)

NDC 60512-9081-5

Directions

- Do not use more than directed
- Do not take with food.
- directed by a health professional. ■ Take before bedtime. Repeat every 8 hours, as needed. Reduce intake with improvement or as

Cough & Co

Cough & C

| en under 2 years of age | en 2 to 5 years of age | en 6 years of age and older | |
|-------------------------|------------------------|-----------------------------|------|
| Ask a doctor | 1/2 teaspoon (tsp) | 1 teaspoon (tsp) | Dose |

Childr Childr

- Other Information

 Store at room temperature.

 Do not use if seal is broken or missing.

Inactive Ingredients

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

Trusted by Mothers!

- Safe, Effective Relief
- No Side Effects
- Great Taste



3025 de l'Assomption Blvd., Montreal, QC H1N 2H2 Canada 1-800-404-4666 / www.kidsrelief.com

Fast acting, formula

effective relief that helps:

effective relief that helps:

Fast acting,

formula

- Relieve dry cough
- Relieve chest congestion
- Thin and loosen mucus

 Thin and loosen mucus Relieve chest congestion Relieve dry cough

Relieve pain and reduce fever

Relieve pain and reduce fever

SAFE - no side effects, no drug interaction Dye free, sugar free

SAFE - no side effects, no drug interaction

Dye free, sugar free

Great 2 Taste AAAT



MANT



Homeopathic Medicine







Homeopathic Medicine











(100 ml) 3.4 fl oz





**AOMEOLAB

HLAB KIDS U.S.

Item no. 512-09081 Rev. 08/12

8159110760

COUGH AND COLD NIGHTTIME FORMULA KIDS RELIEF

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| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60512-9021 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | | |
|--|--|-----------------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| DROSERA ROTUNDIFOLIA (UNII: QR44N9 XPJQ) (DROSERA ROTUNDIFOLIA - UNII: QR44N9 XPJQ) | DROSERA ROTUNDIFOLIA | 1 [hp_C] in 100 mL | | | |
| ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:080TY208ZW) | ARNICA MONTANA | 3 [hp_C] in 100 mL | | | |
| BRYONIA ALBA ROOT (UNII: T7J046 YI2B) (BRYONIA ALBA ROOT - UNII:T7J046 YI2B) | 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 | | | |
| ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H) | ATROPA BELLADONNA | 3 [hp_C] in 100 mL | | | |
| PROTORTONIA CACTI (UNII: LZB7TFX1LT) (PROTORTONIA CACTI - UNII:LZB7TFX1LT) | PROTORTONIA CACTI | 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 MO NO HYDRATE (UNII: 2968 PHW8 QP) | | | | |

| P | Packaging | | | | |
|---|------------------|---------------------|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:60512-9021-9 | 250 mL in 1 BOTTLE | | | |
| 2 | NDC:60512-9021-5 | 100 mL in 1 BOTTLE | | | |
| 3 | NDC:60512-9021-4 | 30 mL in 1 BOTTLE | | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 02/28/2011 | |
| | | | |

Labeler - HOMEOLAB USA INC (202032533)

| Establishment | | | |
|------------------|---------|-----------|--------------------------|
| Name | Address | ID/FEI | Business Operations |
| HOMEOLAB USA INC | | 202032533 | manufacture (60512-9021) |

Revised: 8/2012 HOMEOLAB USA INC