

PAIN AND FEVER KIDS RELIEF BABY- arnica montana, ferrum phosphoricum, hypericum perforatum, belladonna, thuja occidentalis, ledum palustre 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:

Arnica montana 8X (Leopard's bane)

Ferrum phosphoricum 8X (Ferrosferric phosphate)

Hypericum perforatum 8X (St. John's Wort)

Belladonna 8X (Deadly nightshade) Calculated as 0,0000003% alkaloids

Thuja occidentalis 8X (White cedar)

Ledum palustre 8X (Wild rosemary)

Purpose

Fever, aches and pains

Headache, sore throat

Fever, inflammation

Pain in the extremities, toothache, fever

Fever, shooting pain, headache, sore throat

Sinus congestion, headache, muscular pain

Chills and fever

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 temporarily reduce fever and relieve minor aches and pains associated with*:

- common cold
- sore throat
- headache
- toothache

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.

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 12 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, cherry flavor, sodium benzoate, potassium sorbate, citric acid.

CARTON



PAIN AND FEVER KIDS RELIEF BABY

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60512-9201
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	8 [hp_X] in 25 mL
FERRUM PHOSPHORICUM (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	8 [hp_X] in 25 mL
HYPERICUM PERFORATUM (UNII: YK4JY8MNP) (HYPERICUM PERFORATUM		8 [hp_X]

HYPERICUM PERFORATUM (UNII: AK4UX8MNB) (HYPERICUM PERFORATUM - UNII: XK4IUX8MNB)	HYPERICUM PERFORATUM	8 [hp_X] in 25 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII: WQZ3G9PF0H)	ATROPA BELLADONNA	8 [hp_X] in 25 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII: 1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	8 [hp_X] in 25 mL
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII: 877L01IZ0P)	LEDUM PALUSTRE TWIG	8 [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 ACETATE (UNII: DSO12WL7AU)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60512-9201-8	1 in 1 BOX	09/01/2016	
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		09/01/2016	

Labeler - HOMEOLAB USA INC (202032533)

Establishment

Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC		202032533	manufacture(60512-9201)

Revised: 9/2016

HOMEOLAB USA INC