TEETHING KIDS RELIEF BABY- chamomilla, arnica montana, borax, hypericum perforatum 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:

Chamomilla (German chamomile) 5C

Arnica montana (Leopard's bane) 5C

Borax (Sodium borate) 5C

Hypericum perforatum (St John's wort) 5C

Purpose

Gum pain, restlessness, irritability and agitation

Toothache and fever

Gum inflammation and diarrhea

Dental nerve 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 indispositions caused by teething*:

- gum inflammation
- gum pain
- fever
- diarrhea
- restlessness and irritability

Warnings

Do not use if imprinted shrink 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 3 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, sodium benzoate, potassium sorbate, citric acid, orange oil.

CARTON



TEETHING KIDS RELIEF BABY

chamomilla, arnica montana, borax, hypericum perforatum liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60512-9202	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	5 [hp_C] in 25 mL	
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	5 [hp_C] in 25 mL	
SODITIM RODATE (LINII- 0.1MR 7.8 H2OO) (RODATE ION _ LINIII-44O A E20 D22)	SUDII IM BUDATE	5 [hp_C]	

SUDIUM DURATE (UMI. 5 IIVIDZULDŲU) (DURATE IUM - UMII.44UAESVDZZ)	SODIONI DORATE	in 25 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8 MNB) (HYPERICUM PERFORATUM - UNII: XK4IUX8 MNB)	HYPERICUM PERFORATUM	5 [hp_C] 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	ORANGE	Imprint Code	
Contains			

l	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:60512-9202-8	1 in 1 BOX	09/01/2016		
ı	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(60512-9202)	

Revised: 9/2016 HOMEOLAB USA INC