EARACHE KIDS RELIEF - ferrum phosphoricum, capsicum annuum, pyrogenium, arsenicum album, belladonna 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

Ferrum phosphoricum (Ferrosoferric phosphate) 30X

Capsicum annuum (Cayenne pepper) 30X

Pyrogenium (Pyrogen) 30X

Arsenicum album (Arsenous oxide) 30X

Belladonna (Deadly nightshade) 30X

PURPOSE

Inflammation and fever.

Acute pain and pressure in the ears.

Infection and fever.

Burning pain in the ears.

Throbbing pain and inflammation.

This product is manufactured according to the Homeopathic Pharmacopoeia of the United States (HPUS).

USES

This homeopathic medicine helps relieve symptoms associated with earaches:

- throbbing pain
- inflammation
- pressure in ears
- fever

WARNINGS

Do not use if seal is broken or missing.

Stop use and ask a doctor in cases of high fever or if symptoms worsen or persist for more than 2 days.

Keep out of reach of children.

DIRECTIONS

Do not use more than directed.

Do not take with food.

Take .75 ml orally.

Repeat every 8 hours and reduce with improvement or as directed by a healthcare professional.

Infants and children 0 to 9 years of age: .75 ml

OTHER INFORMATION

Store at room temperature.

INACTIVE INGREDIENTS

Purified water, sorbitol, grape and raspberry flavor, sodium benzoate, potassium sorbate, citric acid.

CARTON



LABEL

Drug Facts (continued)

Warnings

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■ Infants and children 0 to 9 years of age: take .75 ml orally. ■ Repeat every 8 hours and reduce with improvement or as directed by a healthcare professional.



NON VARNISH AREA DO NOT PRINT THIS BOX

RETAIN CARTON FOR COMPLETE INSTRUCTIONS Drug Facts

Active Ingredients HPUS: Purpose
Ferrum phosphoricum 30X.......inflammation
(Ferrosoferric phosphate) & fever
Capsicum annuum 30X......acute pain and
(Cayenne pepper) pressure in the ears
Pyrogenium 30X (Pyrogen)....infection & fever
Arsenicum album 30X.....burning pain
(Arsenous oxide) in the ears
Belladonna 30X.....throbbing pain
(Deadly nightshade) and inflammation

HOMEOLAB USA

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Item no. 512-09063 Rev. 3/10

EARACHE KIDS RELIEF

ferrum phosphoricum, capsicum annuum, pyrogenium, arsenicum album, belladonna liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:60512-9063

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FERRUM PHO SPHO RICUM (UNII: 91GQH815F7) (FERRUM PHO SPHO RICUM - UNII: 91GQH815F7)	FERRUM PHOSPHORICUM	30 [hp_X] in 25 mL	
RED PEPPER (UNII: 6M47G7C4SY) (RED PEPPER - UNII:6M47G7C4SY)	RED PEPPER	30 [hp_X] in 25 mL	
RANCID BEEF (UNII: 29 SUH5R3HU) (RANCID BEEF - UNII:29 SUH5R3HU)	RANCID BEEF	30 [hp_X] in 25 mL	
ARSENIC TRIO XIDE (UNII: S7V92P67HO) (ARSENIC TRIO XIDE - UNII:S7V92P67HO)	ARSENIC TRIOXIDE	30 [hp_X] in 25 mL	
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	30 [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 MO NO HYDRATE (UNII: 2968 PHW8 QP)			

Product Characteristics		
Color	Score	
Shape	Size	

Flavor	GRAPE, RASPBERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:60512-9063-8	1 in 1 CARTON		
1	25 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/18/2008	

Labeler - HOMEOLAB USA INC (202032533)

Establishment			
Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC		202032533	manufacture

Revised: 5/2010 HOMEOLAB USA INC