

WELLNESS EARACHE- capsicum annuum, silicea, verbascum thapsus, ferrum phosphoricum, kali muriaticum, aconitum napellus, belladonna, calcarea carbonica, pulsatilla (pratensis) tablet, chewable

Source Naturals, 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:

Capsicum Annuum 6X, Silicea 6X, Verbascum Thapsus 6X, Ferrum Phosphoricum 12X, Kali Muriaticum 12X, Aconitum Napellus 30X, Belladonna 30X, Calcarea Carbonica 30X, Pulsatilla (Pratensis) 30X.

INDICATIONS:

For the temporary relief of ear pain, blockage, ear inflammation, irritability and fever associated with earaches.

WARNINGS:

In case of overdose, get medical help or contact a Poison Control Center right away.

A high fever may be the sign of a serious health condition. If fever or ear pain persist for more than 2 days or new symptoms occur, consult a physician.

As with any medicine, if you are pregnant, may become pregnant, or breastfeeding, seek the advice of a physician before using this product.

Keep this and all medicines out of the reach of children.

Tamper Evident: Do not use if foil blister backing is broken. Foil backing is printed with product name and lot number.

KEEP OUT OF REACH OF CHILDREN:

Keep this and all medicines out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Chew 1 tablet slightly and let it dissolve in the mouth or under the tongue. For infants, crush a tablet between two spoons, add water or juice if desired, and place in mouth. Repeat every 2 to 4 hours as needed, for up to 48 hours. For optimal results take 3-4 doses per day.

One or two doses per day may be taken for up to 4 weeks if symptoms recur or do not resolve completely.

Give Wellness EarAche to children or infants over 6 months of age. This product is not recommended for use by infants under 6 months of age without the advice of your physician.

For Best Results: Keep mouth free of food and strong tastes (such as toothpaste, mouthwash and tobacco) for 15 minutes before and after taking this medicine. These substances may interfere with sublingual absorption.

INDICATIONS:

For the temporary relief of ear pain, blockage, ear inflammation, irritability and fever associated with earaches.

INACTIVE INGREDIENTS:

Lactose and Magnesium Stearate.

QUESTIONS:

Source Naturals, Inc.
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PACKAGE LABEL DISPLAY:**SOURCE NATURALS**

NDC 64471-263-48

with

PainSoothe

Homeopathic Belladonna & Mullein

Children's Formula

Wellness

EarAche

Pain • Blockage • Inflammation • Irritability • Fever

48 HOMEOPATHIC TABLETS

SOURCE NATURALS®



with
PainSoothe™
Homeopathic
Belladonna & Mullein

NDC 64471-263-48

Children's
Formula

A graphic featuring a glowing sun or moon rising over a horizon, framed by a rainbow arch, set against a dark, starry background.

Wellness
EarAche™

Pain • Blockage • Inflammation • Irritability • Fever

48 HOMEOPATHIC TABLETS

Wellness EarAche™

Homeopathy is a special approach to Wellness that works by stimulating your body's own natural defenses to fight earache symptoms.

Indications: For the temporary relief of ear pain, blockage, ear inflammation, irritability and fever associated with earaches.

Directions: Chew 1 tablet slightly and let it dissolve in the mouth or under the tongue. For infants, crush a tablet between two spoons, add water or juice if desired, and place in mouth. Repeat every 2 to 4 hours as needed, for up to 48 hours. For optimal results take 3-4 doses per day. One or two doses per day may be taken for up to 4 weeks if symptoms recur or do not resolve completely. Give **WELLNESS EARACHE** to children or infants over 6 months of age. This product is not recommended for use by infants under 6 months of age without the advice of your physician.

For Best Results: Keep mouth free of food and strong tastes (such as toothpaste, mouthwash, and tobacco) for 15 minutes before and after taking this medicine. These substances may interfere with sublingual absorption.

Ingredients: Active: Capsicum annuum (Cayenne Pepper) 6X, Silicea (Silica) 6X, Verbascum thapsus (Mullein) 6X, Ferrum Phosphoricum (Ferrosiferrous Phosphate) 12X, Kali Muriaticum (Potassium Chloride) 12X, Aconitum napellus (Aconite) 30X, Belladonna (Nightshade) 30X, Calcarea Carbonica (Calcium Carbonate) 30X, Pulsatilla (Wind Flower) 30X; Inactive: Lactose and Magnesium Stearate.

Contains milk.

Warnings: In case of overdose, get medical help or contact a Poison Control Center right away. A high fever may be the sign of a serious health condition. If fever or ear pain persist for more than 2 days or new symptoms occur, consult a physician.

As with any medicine, if you are pregnant, may become pregnant, or breastfeeding, seek the advice of a physician before using this product.

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WELLNESS EARACHE

capsicum annuum, silicea, verbascum thapsus, ferrum phosphoricum, kali muriaticum, aconitum napellus, belladonna, calcarea carbonica, pulsatilla (pratensis) tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64471-263
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	6 [hp_X]
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	6 [hp_X]
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	6 [hp_X]
FERRUM PHOSPHORICUM (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	12 [hp_X]
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	12 [hp_X]
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	30 [hp_X]

ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	30 [hp_X]
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	30 [hp_X]
PULSATILLA PRATENSIS (UNII: 8E272251DI) (PULSATILLA PRATENSIS - UNII:8E272251DI)	PULSATILLA PRATENSIS	30 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND (TABLET)	Size	10mm
Flavor	grape	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64471-263-48	2 in 1 CARTON	11/17/2016	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/17/2016	

Labeler - Source Naturals, Inc. (969024228)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(64471-263) , api manufacture(64471-263) , label(64471-263) , pack(64471-263)

Revised: 11/2016

Source Naturals, Inc.