

**4 KIDS EARACHE RELIEF- atropa belladonna,oyster shell calcium carbonate, crude,lycopodium clavatum spore,anemone pulsatilla,sulfur and matricaria chamomilla liquid
Hyland's**

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.

4 Kids Earache Relief

Purpose

Relieves earache due to swimmer's ear, cold, flu & allergy

Drug Facts

Active ingredients

Belladonna 30C HPUS
(less than 0.000000000001% Alkaloids,
calculated)
Calcarea Carbonica 30C HPUS
Chamomilla 30C HPUS
Lycopodium 30C HPUS
Pulsatilla 30C HPUS
Sulphur 30C HPUS

Purpose

minor fever
throbbing ear pain
occasional sleeplessness and
irritability
ear pain
ear itching, pain worse at night
ear pain with burning

"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopœia of the United States.

Uses

Temporarily relieves symptoms of earache in children, including: ■ minor fever ■ ear pain or throbbing ■ common pain or itching of "swimmer's ear" ■ irritability or occasional sleeplessness associated with earaches after diagnosis by a physician

Warnings

Keep away from eyes. Do not take by mouth.

Earache drops are only to be used in ears.

As with any drug, ask a doctor before use if pregnant or breast-feeding.

Do not use if you have ear tubes, damaged ear drums or after ear surgery.

Consult a physician if: ■ symptoms persist for more than 48 hours or worsen. ■ discharge from ear is present. ■ symptoms are accompanied by a high fever (over 101°F).

Drug Facts (continued)

Keep this and all medications out of the reach of children. If swallowed, contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

Directions

■ **Shake well before using.**

Children ages 2 years and over: Tilt head sideways and apply 3-4 drops into involved ear (Tip of applicator should not enter ear canal). Keep head tilted for at least 2 minutes to keep drops in ear. Repeat until relieved, up to 4 times daily.

Other information

■ **Do not use if imprinted "SEALED FOR YOUR PROTECTION" tamper-evident bottle cap band is broken or missing.**

■ **Store at room temperature.**

■ **Do not refrigerate.**

Inactive ingredients

Citric Acid, Glycerine, Purified Water, Sodium Benzoate.

Questions or comments?

(800) 624-9659

***CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.**

Principal Display Panel

HOMEOPATHIC

NDC 54973-3392-1

2-12

YEARS

NEW

LOOK

4 KIDS

SINCE 1903

Hyland's

Earache

Relief*

Relieves earache
due to swimmer's ear,
cold, flu & allergy

NO DYES or PARABENS

NO NUMBING EFFECT

NATURAL

RELIEF*

0.33 FL. OZ. (10 mL)

***SEE NOTE ON SIDE**

PANEL BELOW DRUG FACTS



occasional sleeplessness associated with earaches after diagnosis by a physician

Warnings

Keep away from eyes. Do not take by mouth. Earache drops are only to be used in ears.

As with any drug, ask a doctor before use if pregnant or breast-feeding.

Do not use if you have ear tubes, damaged ear drums or after ear surgery.

Consult a physician if:

- symptoms persist for more than 48 hours or worsen.
- discharge from ear is present.
- symptoms are accompanied by a high fever (over 101°F).

keep drops in ear. Repeat until relieved, up to 4 times daily.

Other information

- Do not use if imprinted "SEALED FOR YOUR PROTECTION" tamper-evident bottle cap band is broken or missing.
- Store at room temperature.
- Do not refrigerate.

Inactive ingredients

Citric Acid, Glycerine, Purified Water, Sodium Benzoate.

Questions or comments?
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Earache Relief*

Relieves earache due to swimmer's ear, cold, flu & allergy

NO DYES or PARABENS
NO NUMBING EFFECT



0.33 FL. OZ. (10 mL)

***SEE NOTE ON SIDE PANEL BELOW DRUG FACTS**

Package Contains One Bottle
Actual Size

FILL LINE

Manufactured for Hyland's, Inc.
Los Angeles, CA 90061
(800) 624-9659
www.hylands.com

REV. 003



4 KIDS EARACHE RELIEF

atropa belladonna, oyster shell calcium carbonate, crude, lycopodium clavatum spore, anemone pulsatilla, sulfur and matricaria chamomilla liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3392
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	30 [hp_C] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	30 [hp_C] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	30 [hp_C] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	30 [hp_C] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 [hp_C] in 1 mL
LYCOPodium CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPodium	LYCOPodium CLAVATUM	30 [hp_C]

CLAVATUM SPORE - UNII:C88X29Y479)

SPORE

in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3392-1	1 in 1 CARTON	03/01/2019	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2019	

Labeler - Hyland's (008316655)

Revised: 11/2022

Hyland's