

**HYLANDS NATURALS EARACHE DROPS- belladonna leaf,calcium carbonate,chamomile,lycopodium clavatum spore,anemone patens whole,sulfur liquid  
Hyland's 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.*

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**Hyland's Naturals Earache Drops**

**Drug Facts**

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<b>Active ingredients</b>	<b>Purpose*</b>
Belladonna 30C HPUS (less than 0.000000000001% Alkaloids, calculated)	ear pain
Calcarea Carbonica 30C HPUS	ear pain, sensitivity to cold
Chamomilla 30C HPUS	ear pain, sensitivity to drafts, plugged ears
Lycopodium 30C HPUS	ear pain
Pulsatilla 30C HPUS	ear itching
Sulphur 30C HPUS	ear pain with burning, sensitivity to water

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***HPUS" is the Homeopathic Pharmacopoeia of the United States.***

**Uses\***

Temporarily relieves:

- common pain or itching from swimmer's ear
- clogged ears
- ear pain or itching from other earaches, after diagnosis by a physician

**Warnings**

**Keep away from eyes.**

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

Stop use and ask a doctor if:

- symptoms persist for more than 48 hours or worsen.
- any discharge from ear is present.
- symptoms are accompanied by a fever.

**If pregnant or breastfeeding,** ask a health professional before use.

**Keep out of reach of children.**

### ***Drug Facts (continued)***

#### ***Directions***

##### **Adults and children ages 4 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 per day.
- Use as directed.
- Do not refrigerate.
- Shake well before using.

#### ***Inactive ingredients***

Citric Acid, Glycerine, Purified Water.

#### ***Questions?***

www.hylands.com  
or care@hylands.com

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

**DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.**

Temporarily relieves: common pain or itching from swimmer's ear, clogged ears, ear pain or itching from other earaches, after diagnosis by a physician

#### **Principal Display Panel**

**Hyland's Naturals**

**Earache Drops 0.33 FL. OZ. (10 mL)**

Hyland's  
NATURALS™

# Earache Drops\*

Hyland's  
NATURALS™

#1 EARACHE RELIEF\*

# Earache Drops\*

RELIEVE EAR  
PAIN & CLOGGING\*

Swimmer's Ear\*  
Cold & Flu\*  
Allergy\*



0.33 FL. OZ. (10 mL)

HOMEOPATHIC

Trust #1 bestselling  
Earache Dropst  
for fast and  
effective relief  
of earaches due  
to swimming,  
clogged ears, cold  
& flu, or allergies.\*



Safe

Effective Relief\*

Natural Active  
Ingredients



PLEASE  
RECYCLE

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Manufactured for: Hyland's, Inc.  
PO Box 61067, Los Angeles, CA 90061  
www.hylands.com

REV001

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**Manufactured for:** Hyland's, Inc., PO Box 61067, Los Angeles, CA 90061  
www.hylands.com REV001 NDC 54973-4124-1

**HYLANDS NATURALS EARACHE DROPS**

belladonna leaf,calcium carbonate,chamomile,lycopodium clavatum spore,anemone patens whole,sulfur liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-4124
<b>Route of Administration</b>	AURICULAR (OTIC)		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>PULSATILLA PATENS WHOLE</b> (UNII: 4M1169RWJD) (PULSATILLA PATENS WHOLE - UNII:4M1169RWJD)	PULSATILLA PATENS WHOLE	30 [hp_C] in 1 mL

<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 [hp_C] in 1 mL
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	30 [hp_C] in 1 mL
<b>BELLADONNA LEAF</b> (UNII: 6GZW20TIOI) (BELLADONNA LEAF - UNII:6GZW20TIOI)	BELLADONNA LEAF	30 [hp_C] in 1 mL
<b>CHAMOMILE</b> (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	30 [hp_C] in 1 mL
<b>LYCOPODIUM CLAVATUM SPORE</b> (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	30 [hp_C] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-4124-1	1 in 1 CARTON	07/27/2023	
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		07/27/2023	

**Labeler** - Hyland's Inc. (008316655)

### Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-4124) , pack(54973-4124) , label(54973-4124)

Revised: 7/2023

Hyland's Inc.