

**EARACHE DROPS- belladonna leaf, calcium carbonate, chamomile, lycopodium clavatum spore, anemone patens, and 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.

Hyland's Naturals Earache Drops

Purpose

Temporarily relieves common pain or itching from swimmer's ear, and symptoms of other earaches after diagnosis by a physician, including: ear pain or itching, irritability, minor fever

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 common pain or itching from swimmer's ear, and symptoms of other earaches after diagnosis by a physician, including: ■ ear pain or itching ■ irritability ■ minor fever

Warnings

Keep away from eyes.

Do not use

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

Directions

Adults and 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 per day. ■ Use as directed. ■ Do not refrigerate. ■ Shake well before using.

Drug Facts (continued)

Inactive ingredients

Citric Acid, Glycerine, Purified Water, Sodium Benzoate.

Questions?

www.hylands.com or (800) 624-9659

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

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

PRINCIPAL DISPLAY PANEL

Hyland's

NATURALS

Earache

Drops

RELIEVE EAR

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BELLADONNA LEAF (UNII: 6GZW20TIOI) (BELLADONNA LEAF - UNII:6GZW20TIOI)	BELLADONNA LEAF	30 [hp_C] in 1 mL
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	30 [hp_C] in 1 mL
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	30 [hp_C] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	30 [hp_C] in 1 mL
ANEMONE PATENS WHOLE (UNII: 4M1169RWJD) (ANEMONE PATENS WHOLE - UNII:4M1169RWJD)	ANEMONE PATENS WHOLE	30 [hp_C] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3172-1	1 in 1 CARTON	06/17/2004	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:54973-3172-2	1 in 1 CARTON	06/17/2004	12/28/2021
2		12 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		06/17/2004	

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3172) , pack(54973-3172)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources		622559110	manufacture(54973-3172) , pack(54973-3172)

Revised: 12/2022

Hyland's Inc.