

**BABY INFANT 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.*

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**BABY INFANT EARACHE DROPS**

■ Temporarily relieves symptoms of earache in children after diagnosis by a physician, including:

- minor fever ■ ear pain or throbbing
- irritability ■ occasional sleeplessness
- common pain or itching of "swimmer's ear"

**Drug Facts**

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<b>Active ingredients</b>	<b>Purpose</b>
Belladonna 30C HPUS (less than 0.0000000000001 % Alkaloids, calculated)	fever
Calcarea Carbonica 30C HPUS	throbbing ear pain
Chamomilla 30C HPUS	occasional sleeplessness and irritability
Lycopodium 30C HPUS	ear pain
Pulsatilla 30C HPUS	ear itching, pain worse at night
Sulphur 30C HPUS	ear pain with burning

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

**Uses**

■ Temporarily relieves symptoms of earache in children after diagnosis by a physician, including:

- minor fever ■ ear pain or throbbing
- irritability ■ occasional sleeplessness
- common pain or itching of "swimmer's ear"

**Warnings**

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

**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 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.

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Children under 6 months	Consult a physician.
Children 6 months 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.

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**Drug Facts (continued)****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.**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL**

**HOMEOPATHIC**

NDC 54973-7516-3

**6+**

**months**

**NEW**

**LOOK**

BABY

SINCE 1903

Hyland's

**Infant  
Earache Drops\***

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

**NO DYES or PARABENS**

**NO NUMBING EFFECT**

**Natural  
Relief**

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

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



## BABY INFANT EARACHE DROPS

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-7516
<b>Route of Administration</b>	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BELLADONNA LEAF</b> (UNII: 6GZ W20TIO) (BELLADONNA LEAF - UNII:6GZ W20TIO)	BELLADONNA LEAF	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>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
<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

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-7516-3	1 in 1 CARTON	03/16/2004	
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		03/16/2004	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-7516) , pack(54973-7516)

### Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources		622559110	manufacture(54973-7516) , pack(54973-7516)