

**AURO HOMEOPATHIC EAR RELIEF DROPS- atropa belladonna, oyster shell calcium carbonate, crude, capsicum, matricaria recutita, potassium dichromate, plantago major, and verbascum thapsus liquid**

**Insight Pharmaceuticals**

*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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**Auro® Earache**

**Drug Facts**

| <b>Active ingredients (in each drop)</b> | <b>Purpose</b>            |
|--|---------------------------|
| Belladonna 18X                           | hardness of hearing       |
| Calcarea carbonica 12X                   | discomfort in ear         |
| Capsicum annuum 6X                       | pressure in ear           |
| Chamomilla 15X                           | calmative                 |
| Kali bichromicum 12X                     | tickling                  |
| Plantago major 4X                        | sensitivity to discomfort |
| Verbascum thapsus 4X                     | clogging                  |

**Uses**

may help with the irritation of clogged ears by relieving the sense of discomfort in the ear, sensitivity to earwax and drafts.

**Warnings**

**Do not take by mouth.** Ear drops are only to be used in the ears.

**Do not use** with ear tubes.

**Stop use and ask a doctor if**

- symptoms persist for more than 48 hours
- there is discharge from the ear
- there is a fever of 102°F or greater

**If pregnant or breast-feeding** ask a doctor before use.

**Keep out of reach of children.** In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

**Directions**

for adults and children  
over 6 months of age

tilt head sideways and  
apply 3-4 drops into the  
affected ear up to 4 times  
daily. Tip of dropper  
should not enter ear  
canal. To keep drops in,  
tilt ear upward after  
application or gently

|                                   |  |
|-----------------------------------|--|
| children under 6 months<br>of age | place cotton in the ear.<br>consult a doctor |
|-----------------------------------|--|

### **Other information**

Do not use if white neck band imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing. Keep carton for full drug facts.

### **Inactive ingredients**

chamomile (flower) extract, citric acid, glycerin, purified water, sodium benzoate

### **Questions?**

call 1-800-344-7239

Distributed by: **INSIGHT Pharmaceuticals, LLC.**  
Trevose, PA 19053-8433

### **PRINCIPAL DISPLAY PANEL - 29.6 mL Bottle Carton**

**Auro<sup>®</sup>**

Homeopathic\*

**Ear**

**Relief Drops**

- May help ease symptoms of clogged ears
- Long lasting relief
- Safe for daily use
- For children over 6 months

1FL OZ (29.6 mL)

# Auro

Homeopathic\*  
**Ear Relief Drops**  
+ SUPPORTING EAR HEALTH

Homeopathic\*  
**Ear Relief Drops**

# Auro

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\*Homeopathic drug products are required by law to conform to the Homeopathic Pharmacopeia of the United States (HPUS). They are not subject to a premarket approval process.

**Limited Warranty** If not completely satisfied with this product, return proof of purchase (cash register receipt and the original UPC) to Insight Pharmaceuticals for a full refund.

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### Drug Facts (continued)

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for adults and children over 6 months of age

tilt head sideways and apply 3-4 drops into the affected ear up to 4 times daily. Tip of dropper should not enter ear canal. To keep drops in, tilt ear upward after application or gently place cotton in the ear.

children under 6 months of age

consult a doctor

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Visit our website at [www.auroear.com](http://www.auroear.com)  
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## AURO HOMEOPATHIC EAR RELIEF DROPS

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### Product Information

|                                |                  |                           |               |
|--------------------------------|------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG   | <b>Item Code (Source)</b> | NDC:63736-326 |
| <b>Route of Administration</b> | AURICULAR (OTIC) |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength                     | Strength                |
|---|---------------------------------------|-------------------------|
| <b>Atropa Belladonna</b> (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)   | Atropa Belladonna                     | 18 [hp_X]<br>in 0.05 mL |
| <b>Oyster Shell Calcium Carbonate, Crude</b> (UNII: 2E32821G6I) (Oyster Shell Calcium Carbonate, Crude - UNII:2E32821G6I) | Oyster Shell Calcium Carbonate, Crude | 12 [hp_X]<br>in 0.05 mL |
| <b>Capsicum</b> (UNII: 00UK7646FG) (Capsicum - UNII:00UK7646FG)   | Capsicum                              | 6 [hp_X]<br>in 0.05 mL  |
| <b>Matricaria Recutita</b> (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)                                     | Matricaria Recutita                   | 15 [hp_X]<br>in 0.05 mL |
| <b>Potassium Dichromate</b> (UNII: T4423S18FM) (Dichromate Ion - UNII:9LKY4BFN2V)   | Potassium Dichromate                  | 12 [hp_X]<br>in 0.05 mL |
| <b>Plantago Major</b> (UNII: W2469WNO6U) (Plantago Major - UNII:W2469WNO6U)   | Plantago Major                        | 4 [hp_X]<br>in 0.05 mL  |
| <b>Verbascum Thapsus</b> (UNII: C9TD27U172) (Verbascum Thapsus - UNII:C9TD27U172)   | Verbascum Thapsus                     | 4 [hp_X]<br>in 0.05 mL  |

### Inactive Ingredients

| Ingredient Name                                   | Strength |
|---|----------|
| <b>Chamomile</b> (UNII: FGL3685T2X)               |          |
| <b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP) |          |
| <b>Glycerin</b> (UNII: PDC6A3C0OX)                |          |
| <b>Sodium Benzoate</b> (UNII: OJ245FE5EU)         |          |
| <b>Water</b> (UNII: 059QF0K00R)                   |          |

### Packaging

| # | Item Code        | Package Description          | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:63736-326-26 | 1 in 1 CARTON                |                      |                    |
| 1 |                  | 29.6 mL in 1 BOTTLE, DROPPER |                      |                    |

### Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| UNAPPROVED HOMEOPATHIC |  | 11/15/2013           |                    |

**Labeler** - Insight Pharmaceuticals (176792315)