

AURO EARACHE RELIEF- matricaria recutita, plantago major, verbascum thapsus, atropa belladonna, chili pepper, oyster shell calcium carbonate, crude, and potassium dichromate 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.

AURO®
EARACHE RELIEF
EAR DROPS

Drug Facts

Active ingredients	Purpose
Chamomilla (Chamomile) 1X, 6X, 12X, 30X	calmative
Plantago major (Plantain) 4X	pain reliever
Verbascum thapsus (Mullein) 4X	pain reliever
Belladonna (Nightshade) 6X, 12X, 30X	anti-inflammatory
Capsicum annuum (Cayenne) 6X	anti-inflammatory
Calcarea carbonica (Calcium carbonate) 12X	pain reliever
Kali bichromicum (Potassium dichromate) 12X	pain reliever

Uses

for the temporary relief of pain, discomfort, and irritability associated with earaches in adults and children, after diagnosis by a doctor

Warnings

Do not take by mouth. Earache 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

tilt head sideways and apply 3-4
drops into the affected ear up to

for adults and children over 6 months of age	drops into the affected ear up to 4 times daily. 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

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

citric acid, glycerin, purified water, sodium benzoate

Questions

call 1-800-344-7239

Distributed by:

INSIGHT Pharmaceuticals Corp.

Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 29.6 mL Bottle Carton

AURO[®]

EARACHE RELIEF

EAR DROPS

HOMEOPATHIC

RELIEVES EARACHE PAIN

- **CALMS & SOOTHES**
- **SAFE & EFFECTIVE FOR ADULTS & CHILDREN**

1 FL OZ (29.6 mL)

AURO[®] EARACHE RELIEF EAR DROPS

Auro Earache Relief ear drops help relieve pain and reduce the inflammation associated with earaches. Relieving earache pain can help calm and soothe an irritable child and lessen the symptoms that cause sleeplessness.

Auro Earache Relief ear drops are safe and effective for adults and children.

Natural homeopathic ingredients work effectively without any known side effects.

Auro Earache Relief ear drops can be taken with internal analgesics or prescription antibiotics.

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EAR DROPS

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-324
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	4 mL in 30 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	0.3256 mL in 30 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	0.3256 mL in 30 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	0.3256 mL in 30 mL
CHILI PEPPER (UNII: 00UK7646FG) (CHILI PEPPER - UNII:00UK7646FG)	CHILI PEPPER	0.3256 mL in 30 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	0.3256 mL in 30 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM DICHROMATE	0.3256 mL in 30 mL

Inactive Ingredients

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

Product Characteristics

Color	WHITE (Clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-324-24	24 in 1 CASE		
1		1 in 1 BOX		
1		30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		06/01/2010	

Labeler - Insight Pharmaceuticals (176792315)

Revised: 6/2010

Insight Pharmaceuticals