AURO EAR WAX REMOVER- carbamide peroxide liquid
Insight Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

AURO®
EAR DROPS
EARWAX REMOVAL AID

Drug Facts

Active ingredient

Carbamide peroxide 6.5% in anhydrous glycerin

Purpose

Earwax removal aid

Uses

for occasional use as an aid to soften, loosen and remove excessive earwax

Warnings

Flammable, keep away from fire or flame.

FOR EAR USE ONLY

Do not use for more than 4 days

Ask a doctor before use if you have

- ear drainage or discharge
- ear pain, irritation or rash in the ear or are dizzy
- an injury or perforation (hole) of the eardrum
- had ear surgery

When using this product avoid contact with the eyes

Stop use and ask a doctor if excessive earwax remains after use

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years of age and older

- tilt head sideways and place 5 to 10 drops into ear
- tip of applicator should not enter ear canal
- keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear
- use twice daily for up to 4 days if needed or as directed by a doctor

- any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe
- **children under 12 years of age** consult a doctor

Other information

- recap tube after each use
- store at room temperature
- keep carton for full drug facts

Inactive ingredients

disodium EDTA, disodium laureth sulfosuccinate, isopropyl alcohol, methylparaben, methyl salicylate, propylene glycol, purified water

Questions?

call 1-800-344-7239

Distributed:
INSIGHT Pharmaceuticals Corp.
Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 22mL Tube Carton

DOCTOR
RECOMMENDED
INGREDIENT

AURO®
EAR DROPS

CARBAMIDE PEROXIDE 6.5%
in anhydrous glycerin

EARWAX
REMOVAL AID

SAFE ■ FAST ■ EFFECTIVE
when used as directed

SAFETY SEALED
TUBE TIP

0.75 fl oz. (22mL)

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EAR DROPS
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EAR DROPS
EARWAX REMOVAL AID

Drug Facts (continued)

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Visit our website at **www.aurodri.com**

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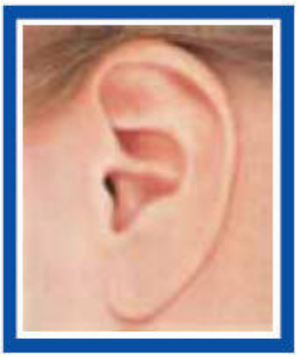
AURO®
EAR DROPS
EARWAX REMOVAL AID

DOCTOR RECOMMENDED INGREDIENT

AURO®
EAR DROPS



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in anhydrous glycerin

EARWAX REMOVAL AID

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SAFETY SEALED TUBE TIP

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AURO®
EAR DROPS
EARWAX REMOVAL AID

See directions on back panel.

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AURO EAR WAX REMOVER

carbamide peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63736-232
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Carbamide peroxide (UNII: 31PZ2VAU81) (Carbamide peroxide - UNII:31PZ2VAU81)	Carbamide peroxide	1.44 mL in 22 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Edetate Disodium (UNII: 7FLD91C86K)	
Disodium Laureth Sulfosuccinate (UNII: D6DH1DTN7E)	
Isopropyl Alcohol (UNII: ND2M416302)	
Methylparaben (UNII: A2I8C7HI9T)	
Methyl Salicylate (UNII: LAV5U5022Y)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63736-232-24	1 in 1 BOX		
1		22 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part344	07/01/2010	

Revised: 1/2011 Insight Pharmaceuticals LLC