

CLINERE EAR WAX REMOVER- carbamide peroxide liquid

Quest Products

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.

Clinere Ear Wax Removal Kit

Active Ingredient

Carbamide Peroxide 6.5%

Purpose

Earwax Removal Aid

Uses

For occasional use as an aid to soften, loosen and remove excess earwax.

Warnings

For use in the ear only

Ask a Doctor before use if you have

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

When using this product

avoid contact with the eyes.

Stop use and ask a Doctor if

- you need to use for more than four days
- excessive earwax remains after use of this product

Keep out of reach of Children.

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

Directions

FOR USE IN THE EAR ONLY.

Adults and children over 12 years of age:

- tilt head sideways and place 5-10 drops into each ear canal.
- Tip of applicator should not enter ear canal.
- Keep drops in ear for several minutes by keeping head tilted or placing cotton in ear.
- Use twice daily for up to four days if needed, or as directed by a doctor.
- Any wax remaining in the ear may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe, or by use of the included Clinere® ear cleaning tool. (See separate directions)

Children under 12 years: Consult a doctor.

Other Information

- Store at 15° - 30°C (59° - 86°F)
- Avoid exposing bottle to excessive heat or direct sunlight
- Store bottle in the outer carton
- Keep cap on bottle when not in use
- Product foams on contact with ear wax due to release of oxygen. There may be an associated crackling sound.

Inactive Ingredients

Anhydrous Citric Acid, Glycerin, Propylene Glycol, Sodium Citrate, Sodium Lauryl Sulfate, Water

Questions?

1-800-328-5890

Weekdays 8:30am -5:00pm CST

Clinere® Earwax Removal Kit w/4 Clinere® Ear Cleaners and 1 x 0.5 Fl Oz Carbamide Peroxide Bottle



CLINERE EAR WAX REMOVER

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68229-102
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	0.065 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68229-102-03	2 in 1 CARTON	03/04/2022	
1	NDC:68229-102-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68229-102-02	1 in 1 CARTON	03/04/2022	
2	NDC:68229-102-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	03/04/2022	

Labeler - Quest Products (075402441)

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