

EAR WAX REMOVAL DROPS- carbamide peroxide liquid

Product Quest Mfg

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.

Active ingredient

Carbamide Peroxide 6.5%.....

Purpose

Earwax removal aid

Uses

For occasional use as an aid to soften, loosen, and remove excessive ear wax

Warnings

Do not use • if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor. • if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor. • for more than four consecutive days.

When using this product • avoid contact with eyes

Stop use and ask a doctor if • excessive ear wax remains after use of this product for four consecutive days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.

Directions FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: 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 ear. Use twice daily for up to four 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

Protect from heat and direct sunlight.

Keep cap on bottle when not in use

Inactive ingredients

Aloe Barbadensis Leaf Extract,
Chamomilla Recutita (Matricaria) Flower Extract, Glycerin,
Mineral Oil, Oxyquinoline Sulfate, Water.

Questions? 866-483-2846

E·R·O
by Scherer Labs

Ear Wax Removal Drops
Carbamide Peroxide 6.5%

Drug Facts	Purpose
Active ingredient Carbamide Peroxide 6.5%	Earwax removal aid
Uses For occasional use as an aid to soften, loosen, and remove excessive ear wax.	
Warnings Do not use • if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor. • if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor. • for more than four consecutive days.	
When using this product • avoid contact with eyes	
Stop use and ask a doctor if • excessive ear wax remains after use of this product for four consecutive days.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.	
Directions FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: 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 ear. Use twice daily for up to four 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 Protect from heat and direct sunlight. Keep cap on bottle when not in use.	
Inactive ingredients Aloe Barbadensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Glycerin, Mineral Oil, Oxyquinoline Sulfate, Water.	
Questions? 866-483-2846	

by Scherer Labs

Ear Wax Removal Drops

Carbamide Peroxide 6.5%

with Chamomile & Aloe

Safe, Fast Acting
Doctor Recommended
Improved Formula
Alcohol Free

0.5 FL OZ (15 mL)

NOTE: E·R·O® Ear Drops will foam on contact with ear wax due to the release of oxygen.

FDA APPROVED USES:
For occasional use as an aid to soften, loosen, and remove excessive ear wax.

ACTUAL SIZE

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

CAUTIONS: Tip of bottle should not enter ear canal. Never use instruments such as cotton swabs, toothpicks, or hairpins to remove wax from the ear canal. When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal. This product is not intended to restore hearing loss due to medical reasons. In such cases, consult a doctor.

SCH-SER02-25

Manufactured by:
Product Quest Mfg, LLC.
330 Carswell Ave.
Daytona Beach, FL 32117
© 2015 Scherer Labs International, LLC.

EAR WAX REMOVAL DROPS

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64048-5118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Carbamide Peroxide (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	Carbamide Peroxide	6.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength

Aloe (UNII: V5VD430 YW9)	
CHAMOMILE (UNII: FGL3685T2X)	
Glycerin (UNII: PDC6A3C0OX)	
Mineral Oil (UNII: T5L8T28 FGP)	
Oxyquinoline Sulfate (UNII: 61VUG75Y3P)	
Water (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64048-5118-1	1 in 1 CARTON	10/05/2011	
1		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	10/05/2011	

Labeler - Product Quest Mfg (927768135)

Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(64048-5118) , label(64048-5118)

Revised: 8/2018

Product Quest Mfg