

ERO EAR WAX REMOVAL KIT- carbamide peroxide 6.5% liquid

Randob Labs

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.

ERO Ear Wax Removal Kit

Carbamide Peroxide 6.5%

Earwax removal aid

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

Ask a doctor before use if you have

- 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.

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

FOR IN EAR USE 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 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.

Aloe Barbadensis Extract, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Glycerin, Propylene Glycol, Sodium Citrate, Sodium Lauryl Sulfate, Tartaric Acid.

<p>Drug Facts</p> <p>Active Ingredient Carbamide Peroxide 6.5% Purpose Earwax removal aid</p> <p>Uses For occasional use as an aid to soften, loosen and remove excessive earwax.</p> <p>Warnings 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 (1-800-222-1222) right away. 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 • Dropper tip of removal drops 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 • Safely scoop out wax with removal tool • Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using the ear bulb syringe • Children under 12 years of age: consult a doctor. Other information • Do not use if neck wrap imprinted safety seal is broken or missing • Do not store above 25° C, 77° F • Store bottle in the outer carton • Keep cap on bottle when not in use • Product foams on contact with earwax due to release of oxygen. Inactive ingredients Aloe Barbadensis Extract, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Glycerin, Propylene Glycol, Sodium Citrate, Sodium Lauryl Sulfate, Tartaric Acid.</p>	<p>CAUTIONS: Dropper tip of removal drops should not enter ear canal. ONLY the earwax removal tool should be used to remove earwax from the ear canal. Never use instruments such as cotton swabs, toothpicks, or hairpins to remove wax from the ear canal. When rinsing the ear with warm water, the tip of the syringe should not obstruct the flow of water leaving the ear canal.</p> <p>Earwax removal tool directions: Wash tool before initial use with warm, soapy water. Rinse and allow to dry completely before using. Repeat between uses. Grasp handle. Gently insert flex tip into ear canal. Sweep and rotate to engage wax. Remove wax and repeat.</p> <p>NOTE: Do not use in abnormal ear canals. Do not use if pain occurs. Discard if cracked or broken. Use only as directed.</p> <p>WARNINGS: Product contains small parts that pose a choking hazard. Keep out of reach of children.</p> <p>For adult use only—not intended for use in children.</p> <p>This product is not intended to restore hearing loss due to medical reasons. In such cases, consult a doctor.</p> <p>FDA-APPROVED USES: For occasional use as an aid to soften, loosen and remove excessive earwax.</p>	<p>ERO BY RANDOB LABS, LTD.</p> <p>EARWAX REMOVAL KIT</p> <p>Carbamide Peroxide 6.5% with Soothing Chamomile & Aloe</p> <p>The Complete 3-PART SYSTEM</p>  <p>Drops, Ear Bulb Syringe and Wax Removal Tool with Safety Shield</p> <p>0.5 FL OZ (15 ML) DROPS, SYRINGE & REMOVAL TOOL</p>	<p>A MORE COMPLETE CLEAN</p> <p>Get rid of excess wax—easy as 1,2,3</p> <p>1 TREAT: Tilt head and put 5-10 earwax removal drops in ear, wait a few minutes</p> <p>2 CLEAR: Safely scoop out wax with removal tool</p> <p>3 CLEANSE: Gently rinse with warm water using ear bulb syringe</p> <p>KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION, SEEK PROFESSIONAL ASSISTANCE OR CONTACT POISON CONTROL CENTER IMMEDIATELY.</p>
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RANDOB LABS
PN 878B

ERO EAR WAX REMOVAL KIT

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52412-175
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
CHAMOMILE (UNII: FGL3685T2X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W4888I119H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-175-01	1 in 1 CARTON	04/16/2021	
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	M014	04/16/2021	

Labeler - Randob Labs (061995007)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(52412-175)

Revised: 5/2023

Randob Labs