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.

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