REXALL EARWAX REMOVAL- carbamide peroxide Dolgencorp LLC

Rexall Earwax Removal Kit

Drug Facts

Active ingredient

Carbamide peroxide 6.5%

Purpose

Earwax removal aid

Uses

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

Warnings

For use in the eay 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 ear drum
- 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 4 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 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: consult a doctor

Other information

- Avoid exposing bottle to excessive heat and direct sunlight
- 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. There may be an associated crackling sound
- Do not use if tamper-evident safety seal is broken or missing

Inactive ingredients

• anhydrous citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, water

Questions?

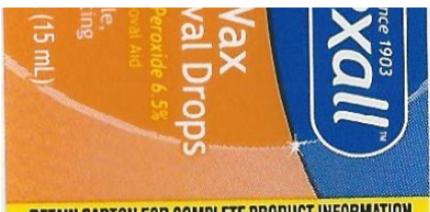
1-866-4-REXALL

Package Labeling:









RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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Visit us at: Rexall.com or call 1-866-4-REXALL REV 09/18
PACKAGED FOR DOLGENCORP, LLC
100 MISSION RIDGE, GOODLETTSVILLE, TN 37072 U.S.A.

LOT:

EXP:

REXALL EARWAX REMOVAL

carbamide peroxide kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-835

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Packaging	
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#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-835-33	1 in 1 BOX	01/01/2019	
1		1 in 1 KIT		

Ouantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	15 mL

Part 1 of 1

REXALL EARWAX REMOVAL DROPS

carbamide peroxide solution/ drops

Product Information

Item Code (Source)	NDC:55910-836
Route of Administration	AURICULAR (OTIC)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ 2VAU81) (HYDROGEN PEROXIDE - UNII: BBX060AN9V)	CARBAMIDE PEROXIDE	65 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	

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# Item	Code	Package Description	Marketing Start Date	Marketing End Date
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1 NDC:55910- 836-33	15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
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Marketing Information						
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date						
OTC Monograph Drug	M014	01/01/2019				

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OTC Monograph Drug	M014	01/01/2019				

Labeler - Dolgencorp LLC (068331990)

Revised: 12/2023 Dolgencorp LLC