

**REXALL EARWAX REMOVAL- carbamide peroxide  
Dolgencorp LLC**

*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.*

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**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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REV 09/18



**Ear Wax Removal Kit**

Carbamide Peroxide 6.5%  
Ear Wax Removal Aid

TAMPER-EVIDENT: DO NOT USE IF NECK SEAL ON BOTTLE IS BROKEN OR MISSING, TAMPERING MAY HAVE OCCURRED.

Visit us at: [Rexall.com](http://Rexall.com)  
or call 1-866-4-REXALL

PACKAGED FOR DOLGENCORP, LLC  
100 MISSION RIDGE  
GOODLETTSVILLE, TN 37072 USA  
MADE IN USA

Since 1903 Rexall™ is a trademark of Rexall Sundown, Inc.



**Ear Wax Removal Kit**

Carbamide Peroxide 6.5%  
Ear Wax Removal Aid

• Safe, gentle, non-irritating

NDC 55910-835-33



**Ear Wax Removal Kit**

Carbamide Peroxide 6.5%  
Ear Wax Removal Aid

• Safe, gentle, non-irritating



WASHER BULB INCLUDED

NET WT 0.5 FL OZ (15 mL)



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Visit us at: [Rexall.com](http://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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-835
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**Packaging**

#	Item 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		

**Quantity 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**

<b>Item Code (Source)</b>	NDC:55910-836
<b>Route of Administration</b>	AURICULAR (OTIC)

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CARBAMIDE PEROXIDE</b> (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	65 mg in 1 mL

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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<b>1</b>	NDC:55910-836-33	15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	01/01/2019	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part344	01/01/2019	

**Labeler** - Dolgencorp LLC (068331990)

Revised: 10/2021

Dolgencorp LLC