

EAR WAX TREATMENT- carbamide peroxide solution/ drops

Rebel Distributors Corp

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.

Rugby® Earwax Treatment Drops

Drug Facts

Active ingredient

Carbamide peroxide 6.5%

Purpose

Earwax removal aid

Use

softens, loosens and removes excessive earwax

Warnings

Do not use for more than 4 days

Ask a doctor before use if you have

- ear drainage or discharge
- ear pain, irritation, rash or are dizzy
- an injury or perforation (hole) of the eardrum or if you had ear surgery

When using this product avoid contact with the eyes

Stop use and ask a doctor if earwax remains longer than 4 days

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:

- 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 tilting head or placing cotton in ear
- use twice daily for up to 4 days
- remove any wax remaining after treatment by gently flushing ear with warm water using a soft rubber bulb ear syringe

children under 12 years: ask a doctor

Other information

- store at room temperature 15° - 30°C (59° - 89°F)
- keep in a dry place

Inactive ingredients

citric acid (anhydrous), glycerin, propylene glycol, purified water, sodium acid pyrophosphate, sodium citrate (anhydrous), trolamine

Questions or comments?

Call **1-800-645-2158**

9am - 5pm ET

Monday - Friday

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL - 15 mL Carton

COMPARE TO
ACTIVE INGREDIENT IN
DEBROX®*

Rugby®

NDC 21695-334-15

Earwax

Treatment

Drops

Carbamide Peroxide 6.5 %

Helps Remove

Excessive Earwax

1/2 fl oz (15 mL)

SATISFACTION GUARANTEED

Rugby

OR YOUR MONEY BACK



EAR WAX TREATMENT

carbamide peroxide solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-334(NDC:0536-3000)
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Carbamide Peroxide (UNII: 31PZ2VAU81) (Carbamide Peroxide - UNII:31PZ2VAU81)	Carbamide Peroxide	81.86 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Glycerin (UNII: PDC6A3C0OX)	
Sodium Acid Pyrophosphate (UNII: H5WVD9LZUD)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Trolamine (UNII: 9O3K93S3TK)	

Product Characteristics

Color	YELLOW (Colorless to pale yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-334-15	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	10/26/2009	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp