

QUALITY CHOICE EARWAX REMOVAL KIT- carbamide peroxide liquid
Chain Drug Marketing Association, Inc.

Quality Choice 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 ear 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:

Children under 12 years: consult a doctor

- 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 titled 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

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?

1-800-328-5890

*This product is not manufactured or distributed by Prestige Brands Inc. owner of the registered trademark Debrox.

Distributed by C.D.M.A., Inc. 43157 W. Nine Mile Novi, MI 48376-0995
www.qualitychoice.com Questions: 248-449-9300

Quality Choice Earwax Removal Kit Earwax Removal aid Carbamide Peroxide 6.5% Safe, Gentle, Non-Irritating Washer Bulb Included 0.5 FL OZ (15mL)

Product Labels

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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 ear 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? 1-800-328-5890

QC QUALITY CHOICE

Earwax Removal Kit

Earwax Removal Aid

Carbamide Peroxide 6.5%
Safe, Gentle, Non-Irritating
Washer Bulb Included

6 355 15 9876 1 6

0.5 FL OZ (15 mL)

QC QUALITY CHOICE

Earwax Removal Kit

Earwax Removal Aid

Carbamide Peroxide 6.5%
Safe, Gentle, Non-Irritating
Washer Bulb Included

0.5 FL OZ (15 mL)

QC QUALITY CHOICE

Earwax Removal Kit

Earwax Removal Aid

Carbamide Peroxide 6.5%
Safe, Gentle, Non-Irritating
Washer Bulb Included

0.5 FL OZ (15 mL)

QUALITY CHOICE EARWAX REMOVAL KIT

carbamide peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (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)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-026-15	1 in 1 CARTON	11/27/2014	
1		15 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	11/27/2014	

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Bell Pharmaceuticals, Inc.		140653770	manufacture(63868-026)

Revised: 12/2023

Chain Drug Marketing Association, Inc.