# BEST CHOICE EARWAX REMOVAL KIT- carbamide peroxide liquid Valu Merchandis ers, Co.

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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#### **Best 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:

- 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

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

Best Choice Earwax Removal Kit ©CARBAMIDE PEROXIDE 6.5% Earwax Removal Aid Safe, Gentle, Non-Irritating washer bulb included 0.5 FL (15 mL)



#### BEST CHOICE EARWAX REMOVAL KIT

carbamide peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-835
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CARBAMIDE PERO XIDE (UNII: 31PZ2VAU81) (HYDROGEN PERO XIDE - UNII:BBX060AN9V)	CARBAMIDE PERO XIDE	65 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)			
WATER (UNII: 059QF0KO0R)			

	Packaging			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:63941-835- 33	1 in 1 CARTON	11/27/2014	
		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 final	part344	11/27/2014	

# Labeler - Valu Merchandisers, Co. (868703513)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bell Pharmaceuticals, Inc.		140653770	manufacture(63941-835)	

Revised: 12/2019 Valu Merchandisers, Co.