

EARWAX REMOVAL KIT- carbamide peroxide 6.5%
CVS

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.

Drug Facts

Active ingredient	Purpose
Carbamide peroxide 6.5%	Earwax removal aid

Uses

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

Warnings

Ask doctor before use if you have • ear drainage or discharge • ear pain • irritation or rash in ear • dizziness • an injury or perforation (hole) of the eardrum • recently had ear surgery

When using this product avoid contact with eyes

Stop and ask doctor before use if • you need to use for more than four days • excessive earwax remains after use of this product

Stop use and ask a doctor if you need to use for more than four days • excessive earwax remains after use of this product

Keep out of reach of the children

If product is 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 of age: consult a doctor.

Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water



Compare to active ingredient
in Debrox® Ear Drops*



Earwax Removal Kit

CARBAMIDE PEROXIDE 6.5%

Earwax removal aid

- Safe, gentle & non-irritating
- Easily cleanses ear with foaming action
- Kit includes soft rubber bulb ear syringe & drops



Actual Product Size
on Side Panels

1 RUBBER BULB SYRINGE & DROPS
0.5 FL OZ (15 mL)



Actual Size
Irrigator

Earwax removal aid

CARBAMIDE PEROXIDE 6.5%

Earwax Removal Kit

CVS Health™
Compare to active ingredient in Debrox® Ear Drops™

TAMPER EVIDENT: DO NOT USE IF CAP'S PRINTED BAND IS MISSING OR DAMAGED

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Active ingredient	Purpose
Carbamide peroxide 6.5%	Earwax removal aid
Uses for occasional use as an aid to soften, loosen and remove excessive earwax	
Warnings	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> • ear drainage or discharge • ear pain • irritation or rash in the ear • dizziness • an injury or perforation (hole) of the eardrum • 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 four days	
• excessive earwax remains after use of this product	
Keep this and all drugs out of the 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:	
<ul style="list-style-type: none"> • tilt head sideways • 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 four 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	
<ul style="list-style-type: none"> • do not store above 86°F (30°C) • store bottle in the outer carton • product foams on contact with earwax due to release of oxygen. There may be an associated "crackling" sound. • keep cap on bottle when not in use 	
Inactive ingredients Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water.	

The CVS Health™ Earwax Removal Kit, when used as directed, cleanses the ear with foaming action to provide a safe, non-irritating method of softening and removing earwax.

Note: Ear drops will foam on contact with earwax due to the release of oxygen.

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

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Made in the U.S.A. with U.S. and imported materials

V-13513



Actual Size Bottle

IMPORTANT: Keep this carton for future reference on full labeling.

EARWAX REMOVAL KIT

carbamide peroxide 6.5% kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-224
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-224-07	1 in 1 KIT	12/24/2014	

Quantity of Parts

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

Part 1 of 1**EAR WAX RMVL CVS**

carbamide peroxide 6.5% liquid

Product Information

Item Code (Source)	NDC:69842-039
Route of Administration	AURICULAR (OTIC)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Carbamide Peroxide (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	Carbamide Peroxide	6.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Lauroyl Sarcosinate (UNII: 632GS99618)	
Sodium Stannate (UNII: NJ7C1V83KG)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-039-01	1 in 1 CARTON		
1		15 mL in 1 BOTTLE; 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	12/24/2014	

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OTC monograph final	part344	12/24/2014	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(69842-039) , label(69842-039) , pack(69842-224)

Revised: 3/2018

CVS