EAR WAX RMVL CVS- carbamide peroxide 6.5% liquid 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 I 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

TAMPER EVIDENT: DO NOT USE IF CAP'S

PRINTED BAND IS MISSING OR DAMAGED **Drug Facts** Active ingredient Purpose Uses for occasional use as an aid to soften, loosen and remove exce Warnings • Ask a doctor before use if you have • ear drainage or discharge • irritation or rash in the ear • 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 FOR USE IN THE EAR UNLT adults and children over 12 years of age: • tilt head sideways • place 5 to 10 drops into ear • tip of applicator should not enter ear canal • keep drops in ear for several to go 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 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 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

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

CVS Quality



Actual Size Bottle

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



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)

EAR WAX RMVL CVS

carbamide peroxide 6.5% liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:69842-039

Route of Administration AURICULAR (OTIC)

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
Carbamide Peroxide (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)
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Inactive Ingredients Ingredient Name Strength ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) Glycerin (UNII: PDC6A3C0OX) Propylene Glycol (UNII: 6DC9Q167V3) Sodium Lauroyl Sarcosinate (UNII: 632GS99618) Sodium Stannate (UNII: NJ7C1V83KG) Water (UNII: 059QF0KOOR)

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:69842-039-01	1 in 1 CARTON	12/24/2014				
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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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)			

Revised: 11/2017 CVS