

CVS EARWAX REM CVS- carbamide peroxide 6.50%

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.

EarWax Removal Drops

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 ear wax

Warnings

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 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 ear wax 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:

- ☐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 ear with warm water, using a soft rubber bulb ear syringe

□ **children under 12 years:** consult a doctor

Other information

- store bottle in the outer carton
- product foams on contact with ear wax due to release of oxygen. There may be an associated "crackling" sound.
- keep cap on bottle when not in use

Inactive ingredients

Aloe Barbadosis Leaf Extract
 Chamomilla Recutita (Matricaria) Flower Extract
 Glycerin
 Mineral Oil
 Oxyquinoline Sulfate
 Water

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DO NOT USE IF TAMPER EVIDENT SHRINK FILM ON BOTTLE IS BROKEN OR MISSING.

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CVS Health Compare to the active ingredient in Murine® Ear Wax Removal System*

Fast Acting Earwax Removal System
 CARBAMIDE PEROXIDE 6.5%
 Earwax removal aid

For occasional use

- Complete 2-step system
- Safely removes excessive earwax

Actual Size on Side Panels

0.5 FL OZ (15 mL) DROPS
 1 IRRIGATOR

Actual Size Bottle

CVS EARWAX REM CVS

carbamide peroxide 6.50% kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-042
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-042-07	1 in 1 KIT	11/12/2014	

Quantity of Parts

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

Part 1 of 1

EARWAX REMOVAL

carbamide peroxide 6.50% solution/ drops

Product Information

Item Code (Source)	NDC:69842-043
Route of Administration	TOPICAL

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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
GLYCERIN (UNII: PDC6A3C0OX)	
OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-043-01	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		

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OTC monograph final	part344	11/12/2014	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(69842-042, 69842-043) , label(69842-042, 69842-043)

Revised: 11/2017

CVS