

**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.

Active ingredient

Purpose

Carbamide Peroxide 6.5%.....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 the ear with warm water, using a soft rubber bulb ear syringe children under 12 years: consult a doctor

Inactive ingredients

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



**Step 1:
Ear wax removal drops**

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. Top of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in ear.

Read additional warnings on drug facts panel

DO NOT USE IF SEAL ON THE DROPS IS BROKEN OR MISSING

**Step 2:
Ear cleansing spray**

Directions: Tilting head to the side, insert tip of nozzle to the downward pointing ear and activate, allowing liquid to flow from ear. Tilt head to the other side and repeat. It is recommended that application takes place over a sink.

Suggested use: 1-2 applications after each use of CVS Health™ Ear Wax Removal Drops or can be used alone 3 or more times per week.

Warnings: CVS Health™ Ear Cleansing Spray should NOT be used in the following situations:

- Children under 12 years of age
- Individuals with tubes in their ears
- Individuals with otitis or other ear infections
- Individuals with (current or previous) perforated eardrums
- Individuals who have had mastoid surgery
- Individuals suffering from Meniere's Syndrome or those experiencing any form of dizziness, vertigo, hardness of hearing or other ear problems
- For the purpose of removing ear wax. Impacted ear wax should be removed by a health care professional prior to use of CVS Health™ Ear Cleansing Spray
- Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Ingredients: Water, Sodium Chloride, DMDM Hydantoin.

Actual Size

Ear Wax Cleansing System

EAR WAX REMOVAL DROPS & EAR CLEANSING SPRAY

- Step 1:
Ear wax removal drops
- Safe, fast acting
 - With chamomile & aloe
- Step 2:
Ear cleansing spray
- Rinses away build up



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CONTAINS:
1 - 0.5 FL OZ (15 mL) BOTTLE
1 - 3.3 FL OZ (98 mL) SPRAY

Ear Wax Cleansing System

EAR WAX REMOVAL DROPS & EAR CLEANSING SPRAY

Ear wax removal drops

Drug Facts
Active ingredient Carbamide Peroxide 6.50% Purpose Ear Wax Removal Aid
Uses For occasional use as an aid to soften, loosen, and remove excessive ear wax.
Warnings Do not use • If you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy, consult a doctor. • If you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor.
When using this product • Avoid contact with the eyes. • Stop use and ask a doctor if excessive ear wax remains after use of this product for four consecutive days.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.
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 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 washing the ear with warm water, using a soft rubber bulb ear syringe. • Children under 12 years of age: consult a doctor.
Other information - Protect from heat and direct sunlight. • Keep cap on bottle when not in use.
Inactive ingredients Aloe Barbadensis Leaf Extract, Chamomile Recutita Matricaria Flower Extract, Glycerin, Mineral Oil, Oxygeninoline Sulfate, Water.
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EARWAX REM CVS

carbamide peroxide 6.50% kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-041
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-041-07	1 in 1 KIT	05/14/2010	

Quantity of Parts

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

Part 1 of 1

EARWAX REM CVS

carbamide peroxide solution/ drops

Product Information

Item Code (Source)	NDC:69842-040
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Route of Administration	TOPICAL
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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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-040-01	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	05/14/2010	

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OTC monograph final	part344	05/14/2010	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(69842-040) , label(69842-040) , pack(69842-041)