# 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.

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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 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**

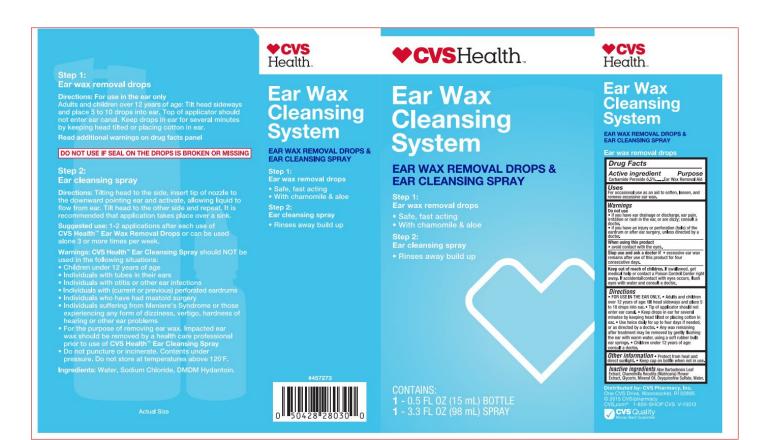
#### FOR USE IN THE EAR ONLY

#### 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



### EARWAX REM CVS

carbamide peroxide 6.50% kit

# **Product Information**

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

#### **Packaging**

l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	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

Route of Administration

TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
Ingicultit name	Dasis of Sticing th	outingin

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)				
CHAMO MILE (UNII: FGL3685T2X)				
Glycerin (UNII: PDC6A3C0OX)				
Oxyquinoline Sulfate (UNII: 61VUG75Y3P)				
MINERAL OIL (UNII: T5L8T28FGP)				
WATER (UNII: 059QF0KO0R)				

l	Pac	kaging			
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 N	DC: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)

Revised: 11/2017 **CVS**