EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid
Care One

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

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

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

Questions?
1-877-846-9949

EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-351
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:41520-351-01	1 in 1 CARTON	08/13/2014	
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	08/13/2014	

Labeler - Care One (809183973)

Registrant - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(41520-351) , label(41520-351)

Revised: 8/2018 Care One