EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid Amerisource Bergen

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.

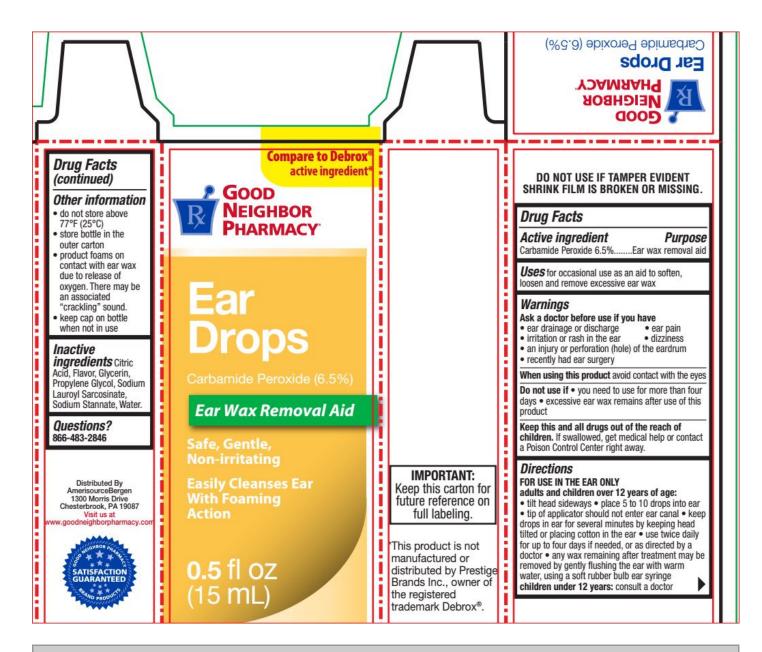
Adults and children over 12 years of age:

- 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? 866-483-2846



EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:24385-502			385-502
Route of Administration	AURICULAR (OTIC)				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Stre	ength	Strength
Carbamide Peroxide (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)			Carbamide Pero	oxide	6.5 g in 100 mL

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: 059QF0KO0R)		

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:24385-502-01	1 in 1 CARTON	05/20/2014		
1	L	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	05/20/2014		

Labeler - Amerisource Bergen (007914906)

Registrant - Product Quest Mfg. (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg.		927768135	manufacture(24385-502), label(24385-502)	

Revised: 8/2018 Amerisource Bergen