FAMILY CARE EARWAX REMOVAL- carbamide peroxide liquid
United Exchange Corp.

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.

Family Care Earwax Removal Drops 639 ZDP

Active ingredient Purpose

Carbamide peroxide 6.5%.....Ear wax removal

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
- dizziness
- irritation or rash in the ear
- recently had ear surgery
- an injury or perforation (hole) of the eardrum

Stop use and ask a doctor if
- you need to use for more than four days
- excessive earwax remains after use of this product

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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 ear
- use twice daily for up to four days if needed, or as directed by a doctor
- any way 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

Other information
- do not store above 25°C (77°F)
- store bottle in the outer carton
- product foams on contact with earwax due to release of oxygen. There may be associated "crackling" sound

- keep cap on bottle when not in use

Inactive ingredients

citric acid monohydrate, flavor, glycerin, propylene glycol, purified water, sodium lauroyl sarcosinate, sodium stannate

Distributed by:

United Exchange Corp.

Cypress, CA 90630

Made in China

FAMILY CARE EARWAX REMOVAL

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-639
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	0.065 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SODIUM STANNATE (UNII: NJ7C1V83KG)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-639-15	1 in 1 CARTON	10/22/2019	
1		15 mL in 1 BOTTLE, DROPPER; 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	10/22/2019	

Labeler - United Exchange Corp. (840130579)

Revised: 3/2022 United Exchange Corp.