

**WAXRX EAR WAX REMOVAL AID DROPS- carbamide peroxide liquid
DOCTOR EASY MEDICAL PRODUCTS, LLC**

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.

Carbamide Peroxide 6.5%

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For occasional use as an aid to soften, loosen and remove excessive ear wax

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 ear drum
- recently had ear surgery

Stop use and ask a doctor if

- you need to use for more than 4 days
- excessive ear wax remains after use of this product

When using this product do not get into eyes

Keep out of reach of children. In case of accidental overdose or allergic reaction, get medical help or contact a Poison Control Center immediately

FOR USE IN THE EAR ONLY

Adults and children over 12 years of age. Tilt head sideways and place 5-10 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 ears. Flush ear with VERY WARM (body temperature) water using the Wax-Rx Ear Washer.

Children under 12, consult a physician. Drops may be used twice daily for up to 4 days or as directed by a physician.

- Avoid exposing bottle to excessive heat or direct sunlight.
- Product foams on contact with ear wax due to release of oxygen. There may be an associated crackling
- Keep cap on bottle when not in use.
- Lot no. and exp. date: see Label, bottom contained or box.

Citric Acid, Glycerin, Propylene Glycol, Sodium Citrate, Sodium Lauryl Sulfate, Tartaric Acid

WaxRx

EAR WAX

REMOVAL

AID DROPS

6.5% Carbamide Peroxide

Safe, Fast Acting

Alcohol Free

0.5 FL OZ (15 ML)

Drug Facts	
Active Ingredients	Purpose
Carbamide Peroxide 6.5%	Earwax Removal Aid
Uses For occasional use as an aid to soften, loosen and remove excessive ear wax.	
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3 x 1-1/4 in.



WAXRX EAR WAX REMOVAL AID DROPS

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72724-001
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU8 1) (HYDROGEN PEROXIDE - UNII:BBX060AN9 V)	CARBAMIDE PEROXIDE	6.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TARTARIC ACID (UNII: W48881119 H)	
GLYCERIN (UNII: PDC6A3C0 O X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8 Q P)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB514J Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167 V 3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72724-001-15	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	12/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	12/12/2018	

Labeler - DOCTOR EASY MEDICAL PRODUCTS, LLC (848752523)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(72724-001)

Revised: 12/2018

DOCTOR EASY MEDICAL PRODUCTS, LLC