EAR WAX REMOVER- carbamide peroxide liquid
Proficient Rx LP

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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drug facts

Active Ingredient

Active ingredient	**Purpose**
Carbamide Peroxide 6.5%	Earwax Removal Aid

Uses

Uses for occasional use as an aid to soften, loosen and remove excessive ear wax.

Keep Out of Reach of Children

Keep out of reach of children. If swallowed, get medical help
or contact a Poison Control Center right away.

Indications and Usage

Uses for occasional use as an aid to soften, loosen and remove excessive ear wax.

Warnings

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 ear drum
- recently had ear surgery

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

When using this product - avoid contact with the eyes. If accidental contact with the eyes occurs, flush eyes with water and consult your doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

Directions
FOR USE IN THE EAR ONLY

Unscrew cap from bottle. Remove foil safety seal from bottle. Affix applicator cap to bottle.

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 ear syringe.
- when the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal

Children under 12 years of age: consult a doctor.

Other information
- avoid exposing the bottle to excessive heat and direct sunlight
- keep cap on bottle when not in use
- lot no. & exp date: see label, bottom of container or box
- retain carton for future reference on full labeling
- **Note:** Drops foam on contact with ear wax due to release of oxygen. There may be an associated "cracking" sound
- **Note:** Oversize packaging for ease in reading label information. Contains one bottle.
- Store between 20 degrees to 25 degrees C (68 degrees to 77 degrees F)

Inactive Ingredients

Inactive ingredients

anhydrous glycerin, citric acid, propylene glycol, sodium lauryl sulfate, sodium citrate, tartaric acid

Questions?

Adverse Drug Event Call toll free: (800) 616-2471

Principal Display Panel

NDC 63187-187-15

EAR WAX REMOVER
WITH IRRIGATOR
Earwax Removal Aid
(carbamide peroxide 6.5%)

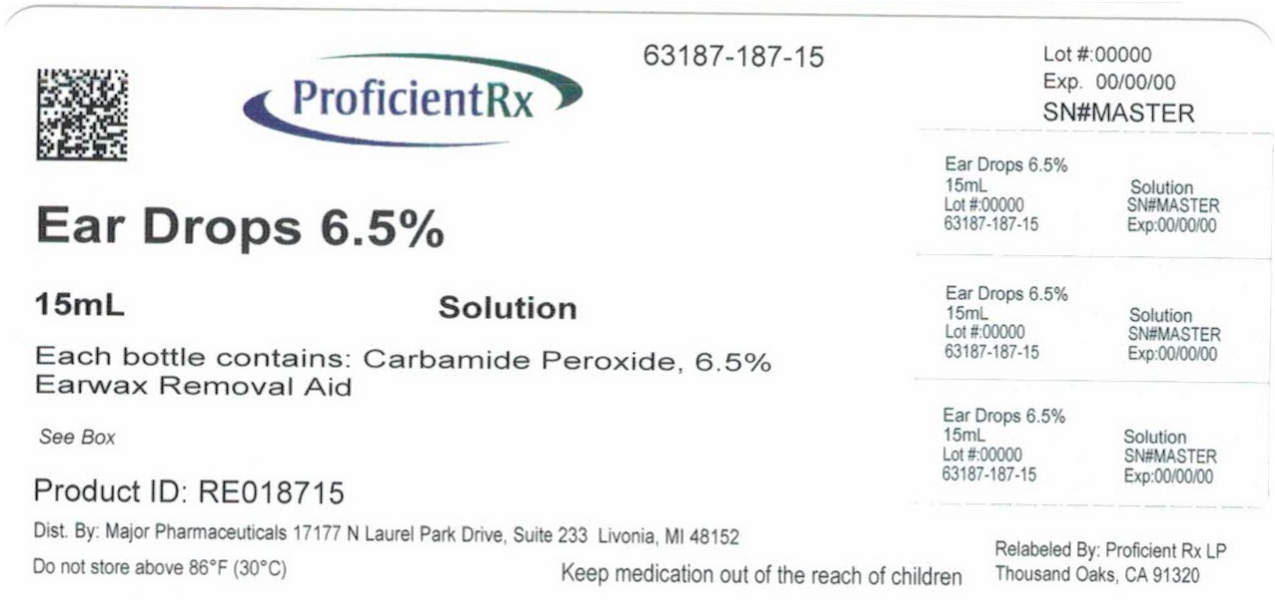
Distributed by:

MAJOR PHARMACEUTICALS
31778 Enterprise Drive
Livonia, MI 48150 USA

Relabeled By:

Proficient Rx LP

Thousand Oaks, CA 91320



EAR WAX REMOVER

carbamide peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-187(NDC:0904-6004)
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	65 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
GLYCERYL 1-DIACETYLTARTRATE 2,3-DISTEARATE (UNII: M25488413L)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-187-15	1 in 1 CARTON	01/01/2019	
1		15 mL in 1 BOTTLE, DISPENSING; 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	05/27/2009	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-187) , RELABEL(63187-187)

Revised: 1/2021 Proficient Rx LP