EAR WAX REMOVAL DROPS- carbamide peroxide - 6.5% solution/ drops
GeriCare Pharmaceutical 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.

Drug Facts

Active ingredient

Carbamide Peroxide, 6.5%

Earwax removal aid

Uses

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

Warnings

Do not use if you have

- eardrainage, discharge, ear pain,irritation
- rashin the ear,or are dizzy
- injuryor perforation (hole) of the ear drum or after ear surgery

When using this product

- do not use for more than four days
- avoid contact with the eyes. If accidental contact with the eyes occurs, flush eyes with water and consult a doctor
- if excessive earwax remains after the use of this product, consult a doctor

Keep out of the reach of children

If 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 earwax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb 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**: consult a doctor.

Other information

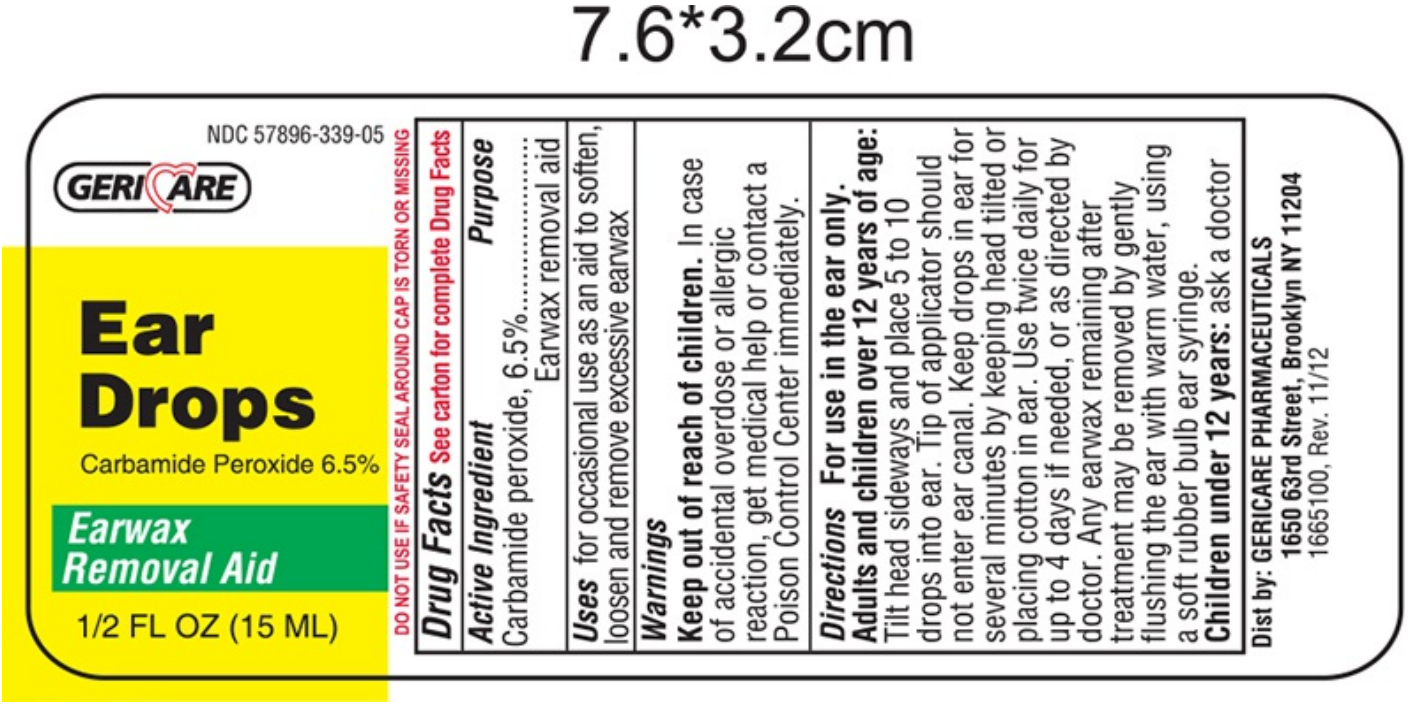
- Protect from heat and direct sunlight
- Keep cap on bottle when not in use.

- Lot No. and EXP date: see label, bottom container or box.

Inactive ingredients

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

Principal Display Panel Bottle Label 0.5 FL OZ



Preferred Plus Pharmacy

Ear Wax Removal drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15ml)

Principal Display Panel - Carton label 0.5 FL OZ

Preferred Plus Pharmacy

Ear wax Remover Drops

Carbamide Peroxide 6.5%

Ear wax removal aid

0.5 FL OZ (15ml)

EAR WAX REMOVAL DROPS

carbamide peroxide - 6.5% solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57896-339
Route of Administration	TOPICAL		

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
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TARTARIC ACID (UNII: W4888I119H)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-339-05	1 in 1 CARTON	05/27/2014	
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	05/27/2014	

Labeler - GeriCare Pharmaceutical Corp (611196254)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(57896-339)

Revised: 12/2017 GeriCare Pharmaceutical Corp