

EAR DROPS EARWAX REMOVAL AID- carbamide peroxide liquid
AmerisourceBergen Drug Corporation (Good Neighbor Pharmacy)

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%

□ Purpose

Earwax removal aid

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

□ Stop use and ask a doctor if

- you need to use of r 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

□ 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**: consult a doctor.

Other information

- Avoid exposing bottle to excessive heat and direct sunlight.
- Product foams on contact with earwax 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 container or box.

Inactive ingredients

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

7.6*3.2cm



GOOD NEIGHBOR PHARMACY

NDC 24385-955-01

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING

ACTIVE INGREDIENT: Carbamide peroxide, 6.5% **USES:** For occasional use as an aid to soften, loosen and remove excessive ear wax. **WARNINGS:** Ask a doctor if you have ear drainage or discharge, ear pain, irritation or rash in the ear, dizziness, had an injury or perforation (hole) of the ear drum or recently had ear surgery. **Stop use and ask a doctor if you need to use for more than 4 days or if excessive ear wax remains after use of the 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.

DIRECTIONS: 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 for several minutes by keeping your head tilted or placing cotton in your ear. Use twice daily 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.

OTHER INFORMATION: Avoid exposing bottle to excessive heat or direct sunlight. Product foams on contact with ear wax due to release of oxygen. Keep cap on bottle when not in use.

INACTIVE INGREDIENTS: See carton.

1300 Morris Drive, Chesterbrook, PA 19087
Visit us at www.goodneighborpharmacy.com

162505B, Rev. 1/12

Ear Drops

Carbamide Peroxide 6.5%

Earwax Removal Aid

1/2 FL OZ (15 ML)

 PANTONE 186 C

 PANTONE 293 C



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6 font HELVETICA Condensed

9 font HELVETICA Condensed

8 font HELVETICA Condensed

6 font HELVETICA Condensed

SIZE:4.4x2.5x10.1cm



Cat. No. 0335-00
152505B, Rev. 1/12

PANTONE 186 C
PANTONE 293 C



EAR DROPS EARWAX REMOVAL AID

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24385-955
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU8 1) (HYDROGEN PEROXIDE - UNII:BBX060AN9 V)	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: W4888119H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24385-955-01	1 in 1 CARTON		
1	NDC:24385-955-02	15 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	01/01/2012	

Labeler - AmerisourceBergen Drug Corporation (Good Neighbor Pharmacy) (007914906)

Registrant - Lee Pharmaceuticals (056425432)

Establishment

Name	Address	ID/FEI	Business Operations
AmerisourceBergen Drug Corporation		007914906	label(24385-955)

Establishment

Name	Address	ID/FEI	Business Operations
Lee Pharmaceuticals		056425432	manufacture(24385-955)

Revised: 6/2013

AmerisourceBergen Drug Corporation (Good Neighbor Pharmacy)