

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

Sheffield Pharmaceuticals LLC

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

- eardrainage, discharge, ear pain,irritation
- rash in the ear,or are dizzy
- 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 remain after use of this product

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
- product foams on contact with ear wax due to release of oxygen, there may be associated cracking
- 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

Sheffield

Earwax Removal Aid Drops

Carbamide Peroxide 6.5%

NET 0.5 FLOZ (15 ml)



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. Questions or comments? 1-800-222-1087 Made in USA OF U.S. & Imported Ingredients and Components



Safe • Fast Acting

Ear Wax Removal Drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15 mL)

DIRECTIONS: FOR USE IN THE EAR ONLY. Adults and children over the age of 12 years: 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.

Distributed by Sheffield Pharmaceuticals
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EAR WAX REMOVAL DROPS

carbamide peroxide - 6.5% solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-143
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:11527-143-51	1 in 1 CARTON	02/02/2017	
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 Drug	M014	02/02/2017	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Revised: 12/2022

Sheffield Pharmaceuticals LLC