

EARWAX REMOVAL KIT - earwax removal kit liquid
McKesson

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.

Earwax Removal Aid

Active ingredient(s)

Carbamide Peroxide 6.5%

Purpose

Earwax Removal Aid

Use(s)

For occasional use to soften, loosen and remove excessive earwax.

Warnings

Warning

For External Use Only

Do not use

- In the eye
- for more than 4 days

Ask a doctor before use if you have

- ear drainage or discharge
- pain, irritation or rash in the ear
- had ear surgery
- an injury or perforation (hole) in the ear drum

Stop use and ask a doctor if

Stop use and ask a doctor if excessive earwax remains after use

Keep out of 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 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 of age, consult a doctor.

Other information

Do not use if imprinted seal on cap is broken or missing.

Storage

- Store at controlled room temperature 15 to 30C (59 to 86F)
- KEEP IN A DRY PLACE

Principal Display Panel

Principle display panel:

HealthMart. PHARMACY
earwax removal kit
carbamide peroxide 6.5%
softens & removes excessive earwax safely and gently

earwax removal kit
See back panel for complete directions

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

Note: When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal.

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

Ear Syringe Cleaning and Storage

1. Clean syringe thoroughly with plain water after each use.
2. Shake out excess water and let air-dry thoroughly.
3. Store in a cool, dry place, away from hot surfaces and sharp instruments.
4. Do not expose product to direct sunlight or heat.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

HealthMart. PHARMACY
NDC 62011-0189-1
earwax removal kit
carbamide peroxide 6.5%
softens & removes excessive earwax safely and gently

earwax removal kit
See back panel for complete directions

Tilt head and squeeze bottle

Gently flush the ear with warm water

FOR YOUR PROTECTION: The bottle in this package has a tamper-resistant seal imprinted, "sealed for your protection", connecting the cap to the bottle. If the seal has been tampered with, DO NOT use this product.

safe, fast acting formula
ear syringe included

Drug Facts

Active ingredient	Purpose
Carbamide Peroxide 6.5%	Earwax Removal Aid

Uses: For occasional use as an aid to soften, loosen, and remove excessive earwax.

Warnings
For external use only

Do not use

- in the eyes
- for more than 4 days

Ask a doctor before use if you have

- ear drainage or discharge
- pain, irritation or rash in the ear
- had ear surgery
- an injury or perforation (hole) of the ear drum

Stop use and ask a doctor if excessive earwax remains after use

Keep out of 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 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

- Store at controlled room temperature 15 to 30C (59 to 86F)
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Inactive ingredients
anhydrous glycerin

1 0.5 fl.oz (15 ml) bottle and 1 ear syringe

MCKESSON
Distributed by McKesson
One Post Street, San Francisco, CA 94104
Money Back Guarantee
www.healthmart.com/healthmartbrand

Ear Drops made in U.S.A.
Ear Syringe made in China



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Earwax Removal Kit Box

Inactive Ingredients

anhydrous Glycerin

EARWAX REMOVAL KIT

earwax removal kit liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:620 11-0 169(NDC:620 11-0 167)
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU8 1) (CARBAMIDE PEROXIDE - UNII:31PZ2VAU8 1)	CARBAMIDE PEROXIDE	6.5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	120.0 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:620 11-0 169-1	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part344	02/06/2012	

Labeler - McKesson (177667227)**Registrant** - Continental Manufacturing Chemist, Inc. (005278007)**Establishment**

Name	Address	ID/FEI	Business Operations
Continental Manufacturing Chemist, Inc.		005278007	MANUFACTURE(620 11-0 169)

Revised: 5/2012

McKesson