

EARWAX REMOVAL- earwax removal liquid

Apothecary Products, LLC

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:

Reg. Dept. _____

Additional Com _____

Earwax Removal Kit

Kit de eliminación de cera del oído

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

PARA SU PROTECCIÓN: La botella en este paquete tiene un sello impreso de seguridad, "sello para su protección", que conecta la tapa a la botella. Si el sello se ha roto, NO use este producto.



Flents.

Earwax Removal Kit

Kit de eliminación de cera del oído

Carbamide Peroxide (6.5%)
Earwax Removal Aid

Peróxido de carbamida (6.5%)
Auxiliar para eliminar cera de los oídos

1 - 0.5 fl oz (15 mL) Earwax Removal Aid & 1 - 0.7 oz (20 mL) Ear Syringe

1 - 15mL auxiliar para eliminar cera de los oídos y 1 - 20 mL jeringa para el oído

Earwax Removal Kit
Kit de eliminación de cera del oído

Carbamide Peroxide (6.5%)
Peróxido de carbamida (6.5%)

Earwax Removal Aid
Auxiliar para eliminar cera de los oídos

See back panel for complete directions
Ver el panel posterior para consultar las instrucciones completas.



Tilt head and squeeze bottle
Levante la cabeza y presione la botella



Gently flush the ear with warm water
Enjuague el oído suavemente con agua tibia

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

Note: Cuando el canal del oído sea irrigado, la punta de la jeringa para oído no deberá obstruir el flujo del agua que sale del canal del oído.

Drug Facts (continued)

Other information

- Store at controlled room temperature 15 to 30C (59 to 86F)
- Do not use if imprinted seal on cap is broken or missing.
- KEEP IN A DRY PLACE

Inactive ingredients
anhydrous glycerin

Please inspect ear syringe prior to use and replace if product shows any signs of wear. Cleaning & Storage: Clean syringe with warm, soapy water & rinse thoroughly after each use. Shake out excess water and let air-dry thoroughly. Store in a cool, dry place, away from hot surfaces and sharp instruments. Do not expose product to direct sunlight or heat.

Por favor, revise bien la jeringa para oído antes de usarla y reemplácela si muestra alguna señal de desgaste.

Limpieza y almacenamiento: Limpie la jeringa con agua tibia y jabón y enjuague con abundante agua después de usarla. Agite para sacar el exceso de agua y deje que seque bien con el aire del ambiente. Guarde en un lugar fresco y seco, lejos de superficies calientes y objetos filosos. No exponga el producto a la luz directa del sol o al calor directo.

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.

Keep cap on bottle when not in use.
Colocar la tapa en la botella cuando no se use.

Earwax Removal Kit
F414-450

Distributed by:
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1-800-328-2742
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www.apothecaryproducts.com



Flents Earwax Removal Kit Box

Inactive Ingredients

anhydrous Glycerin

Questions or Comments?

Call 1-800-328-2742

EARWAX REMOVAL

earwax removal liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49762-450
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	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:49762-450-15	15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part344	08/31/2008	

Labeler - Apothecary Products, LLC (092312735)

Registrant - Continental Manufacturing Chemist, Inc. (005278007)

Revised: 5/2014

Apothecary Products, LLC