

**EARWAX REMOVAL AID- earwax removal aid 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.*

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**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:

**Earwax Removal Aid**

**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.

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

**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

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

Proteger del calor y luz solar directa. Colocar la tapa en la botella cuando no se use.

**Flents.**

**Earwax Removal Aid**

Auxiliar para eliminar cera de los oídos  
Carbamide Peroxide (6.5%)  
Péroxido de carbamida (6.5%)

- **Softens and Removes Excessive Earwax Safely and Gently**  
Suaviza y elimina el exceso de cera del oído con seguridad y cuidado
- **Safe, Fast Acting Formula**  
Fórmula segura y de rápida acción

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

**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.**

**Tilt head and squeeze bottle**  
Ladear la cabeza y presione la botella

**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.

**0.5 FL OZ (15mL)**  
Bottle  
Botella

**Earwax Removal Aid**  
F414-453  
Distributed by:  
Apothecary Products, Inc.\*  
Minneapolis, MN 55337  
1-800-328-2742  
Made in U.S.A. Hecho en E.E.U.U.  
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www.apothecaryproducts.com

Flents Earwax Removal Aid Box

## Inactive Ingredients

anhydrous Glycerin

## EARWAX REMOVAL AID

earwax removal aid liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49762-453
<b>Route of Administration</b>	AURICULAR (OTIC)		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	6.5 mg in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	120.0 mg in 100 mL

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49762-453-15	15 mL in 1 BOTTLE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part344	08/31/2010	

**Labeler** - Apothecary Products, LLC (092312735)**Registrant** - Continental Manufacturing Chemist, Inc. (005278007)

Revised: 5/2014

Apothecary Products, LLC