# 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 my 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

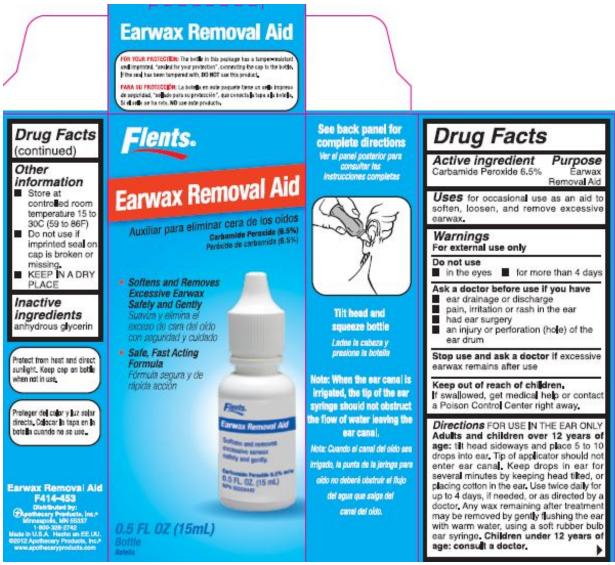
Do not use if imprinted seal on cap is broken or missing.

# Storage

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

## **Principal Display Panel**

Principle display panel:



Flents Earwax Removal Aid Box

### **Inactive Ingredients**

anhydrous Glycerin

#### EARWAX REMOVAL AID

earwax removal aid liquid

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

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CARBAMIDE PERO XIDE (UNII: 31PZ2VAU81) (HYDROGEN PERO XIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	6.5 mg in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6 A3C0 OX)	120.0 mg in 100 mL		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 1	NDC:49762-453-15	15 mL in 1 BOTTLE			

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

Labeler - Apothecary Products, LLC (092312735)

**Registrant** - Continental Manufacturing Chemist, Inc. (005278007)

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