

## CVS EARWAX REMOVAL AID - carbamide peroxide liquid

CVS Pharmacy

*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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### 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 ear wax.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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#### Warnings

##### Ask a doctor before use if you have

- ear drainage or discharge - ear pain
- irritation or rash in the ear - dizziness
- an 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 four days
- excessive wax remains after use of this product

**When using this product** - avoid contact with the eyes

**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

Unscrew cap from bottle. Remove foil safety seal from bottle. Affix applicator cap to bottle.

##### 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 ear syringe.

**Children under 12 years of age:** consult a doctor.

**Other information**

- avoid exposing the bottle to excessive heat and direct sunlight
- keep cap on bottle when not in use
- **Note:** Drops foam on contact with ear wax due to release of oxygen. There may be an associated "cracking" sound
- **Note:** Oversize packaging for ease in reading label information. Contains one bottle.
- Store between 20 degrees to 25 degrees C (68 degrees to 77 degrees F)

**Inactive ingredients**

glycerin, propylene glycol, purified water, sodium lauroyl sarcosinate, citric acid, flavor, sodium stannate



**Drug Facts (continued)**

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\*This product is not manufactured or distributed by GlaxoSmithKline, owner of the registered trademark Debrox®

**IMPORTANT:**  
Keep this carton for future reference on full labeling.



Compare to the active ingredient in Debrox®\*

**EAR DROPS**

**EARWAX REMOVAL AID**

CARBAMIDE PEROXIDE 6.5%

**Non-irritating, gentle, safe method of softening & removing earwax**



0.5 FL OZ (15 mL)



**EAR DROPS**

**EARWAX REMOVAL AID**

Used as directed, CVS/pharmacy Ear Drops provide a non-irritating, gentle, safe method of softening & removing earwax.



Distributed by:  
CVS Pharmacy, Inc.  
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www.cvs.com  
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# 110973



BX107CVS.50Z-2

NON-VARNISH AREA

**DO NOT USE IF SEAL UNDER CAP IS TORN OR MISSING**

**Drug Facts**

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**Warnings**

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  - ear pain
  - irritation or rash in the ear
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**Stop use and ask a doctor if** ■ you need to use for more than four days ■ excessive wax remains after use of this product

**When using this product** ■ avoid contact with the eyes

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  - 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.

**CVS EARWAX REMOVAL AID**

carbamide peroxide liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-257	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU8 1) (CARBAMIDE PEROXIDE - UNII:31PZ2VAU8 1)		CARBAMIDE PEROXIDE	65 mg in 1 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)				
SODIUM STANNATE (UNII: NJ7C1V83KG)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	MINT (FLAVOR)	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59779-257-27	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, DISPENSING		
<b>Marketing Information</b>				
<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	04/25/2011		

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Pharma Pac, LLC (140807475)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

