

## **EAR DROPS MAJOR- carbamide peroxide 6.5% liquid A-S Medication Solutions**

*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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### **Ear Drops Major**

Carbamide Peroxide 6.5%

Earwax Removal Aid

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

Ask doctor before use if you have • ear drainage or discharge • ear pain • irritation or rash in ear • dizziness • an injury or perforation (hole) of the eardrum • recently had ear surgery

When using this product avoid contact with eyes

Stop and ask doctor before use if • you need to use for more than four days • excessive earwax remains after use of this product

Stop use and ask a doctor if you need to use for more than four days • excessive earwax remains after use of this product

Keep out of reach of the children

If product is 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.

Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water

If swallowed, get medical help or contact a Poison Control Center right away.

### **Carbamide Peroxide 6.5%**



## EAR DROPS MAJOR

carbamide peroxide 6.5% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-5273(NDC:0904-6627)
<b>Route of Administration</b>	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM STANNATE</b> (UNII: NJ7C1V83KG)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5273-0	1 in 1 CARTON	10/20/2020	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	10/10/2019	

**Labeler** - A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5273)

Revised: 4/2021

A-S Medication Solutions