

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

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-5273(NDC:0904-6627)
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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM STANNATE (UNII: NJ7C1V83KG)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
WATER (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 Drug	M014	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: 1/2024

A-S Medication Solutions