

DOLOEAR- carbamide peroxide liquid
Pharmadel LLC

DoloEar (WP)(DA)

DRUG FACTS

Active Ingredient and Purpose

<i>Active ingredient</i>	<i>Purpose</i>
Carbamide peroxide 6.5%.....	Earwax removal aid

Uses

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

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

When using this product

avoid contact with the eyes.

Stop use and ask your doctor if

- you need to use for more than 4 days
- excessive earwax remains after use of this product

Keep out of reach of children.

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

Other information

- Store in a cool dry place
- do not use if clear seal over dropper is torn, broken, or missing

Inactive ingredients

glycerin, water

Questions or comments?

+1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

Dist. by/ por:

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Principal Display Panel





DOLOEAR

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-506
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-506-01	1 in 1 CARTON	05/15/2025	06/01/2027
1		15 mL in 1 BOTTLE, DROPPER; 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	05/15/2025	06/01/2027

Labeler - Pharmadel LLC (030129680)

Revised: 5/2025

Pharmadel LLC