

EAR WAX REMOVING DROPS CARBAMIDE PEROXIDE- preferred plus liquid
Kinray Inc

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.

Drug Facts

Active Ingredient

Carbamide Peroxide 6.5%

Purpose

Softens and Loosens Wax

Uses

Safely and gently removes ear wax.

Warnings

Do not use: if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor. If you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor. For more than four consecutive days.

When using this product: avoid contact with the eyes.

Stop use and ask a doctor if: excessive ear wax remains after use of this product for four consecutive days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.

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 ear. Use twice daily for up to four 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.

Inactive ingredients

Glycerin, Oxyquinoline, Aloe Barbadensis Leaf Extract, Anthemis Nobilis Flower Oil

Ear Wax Removal System



EAR WAX REMOVING DROPS CARBAMIDE PEROXIDE

preferred plus liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61715-031
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)	
OXYQUINOLINE (UNII: 5UTX5635HP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-031-74	1 in 1 CARTON		
1		15 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	03/15/2013	

Labeler - Kinray Inc (012574513)

Revised: 3/2013

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