CLEARCANAL EAR WAX SOFTERNER DROPS- carbamide peroxide solution/ drops

NeilMed Pharmaceuticals, Inc.

Drug Facts

Drug Facts:

Active ingredient: CARBAMIDE PEROXIDE

Ear Wax Removal Drops Directions

Step 1 Ear Wax Removal Drops 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 enclosed ear plugs in ear.
- Use twice daily for upto 4 days if needed or as directed by a doctor.
- Any wax remaining after treatment may be removed by gently flushing the ear with NeilMed ClearCanal rinsing system with special ear rinse adapter.
- Children under 12 years of age: consult a doctor.

Avoid exposing bottle to excessive heat and direct sunlight. Keep cap on bottle when not in use.

Inactive Ingredients: Glycerin, Oxyquinoline, Aloe Barbadensis, Chamomile

Softens ear wax. Ear wax removal drops

Children under 12 years of age: consult a doctor.

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.

Do not use:

- * If you have had an allergic reaction to Carbamide Peroxide.
- * 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

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

When using this product:

* Avoid contact with the eyes

Ear Wax Removal Complete System

Ear wax is an important part of your body's system for keeping dirt, bacteria and other things from causing hearing problems. When rinsing is necessary, this cleaning system helps to soften, loosen and remove the excessive ear wax.

The system consists of kit with 1 bottle carbamide peroxide solution 15mL and 1 can sterile saline spray 177mL (or 125mL).

Place 5 to 10 drops of 6.5% carbamide peroxide solution into e

Warnings:

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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

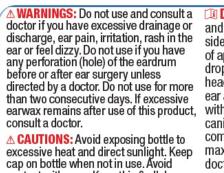
For more than four consecutive days

When using this product:

void contact with the eyes

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

3" W x 1.375" H 0.125" CR



contact with eyes. Keep this & all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center. Do not heat the bottle.

NeilMed **DIRECTIONS:** For use in the ear only. Adults and children over 12 years of age: Tilt head sideways and place 10 drops into each ear. Tip of applicator should not enter ear canal. Keep drops in the ear for 10 minutes by keeping your head tilted or use ear plugs. If needed, rinse ear after treatment by gently flushing the ear with Neil Med® ClearCanal® (supplied in a canister with a special ear rinse adapter) or any other commercial system recommended by your doctor. Use maximum twice per week if needed or as directed by a doctor. Children under 12 years of age: Consult a doctor. NOTE: Ear Drops will foam on contact with earwax due to the release of oxygen.

ACTIVE INGREDIENT: Carbamide Peroxide 6.5%. **INACTIVE INGREDIENT:** Glycerin and Oxyguinoline.

15 mL (0.5 fl oz) NDC 13709-230-01 6011-ENU-US_REV14_GP20181228_kp

Pain Free

Fast Acting

Alcohol Free

SOFTENER

DROPS



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Dr. Mehta's Earwax Removal Complete Kit*

Earwax is important in preventing dirt and bacteria from causing hearing problems. If there is an excess of wax build up, ear rinsing may be necessary to soften, loosen and wash it out.









CLEARCANAL EAR WAX SOFTERNER DROPS

carbamide peroxide solution/ drops

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:13709-230 Route of Administration AURICULAR (OTIC)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ 2VAU81) (HYDROGEN PEROXIDE - UNII: BBX060AN9V)	CARBAMIDE PEROXIDE	65 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
OXYQUINOLINE (UNII: 5UTX5635HP)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:13709- 230-01	1 in 1 BOX	01/02/2012			
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product				
2	NDC:13709- 230-10	1 in 1 KIT	08/24/2012			
2		15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M014	08/24/2011			

Labeler - NeilMed Pharmaceuticals, Inc. (799295915)

Establishment					
Na me	Address	ID/FEI	Business Operations		
NeilMed Pharmaceuticals, Inc.		799295915	manufacture(13709-230)		

Revised: 1/2024 NeilMed Pharmaceuticals, Inc.