

CLEANSE RIGHT EAR WAX DROPS- ear wax drops solution/ drops Blue Echo Care

Active ingredient

Carbamide Peroxide 6.5%

Purpose

Ear Wax Removal Aid

Keep out of the reach of children

If 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 earwax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe.

When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal.

Children under 12 years: consult a doctor.

Inactive Ingredients

Citric Acid, Sodium Citrate Dihydrate, Sodium Lauryl Sulfate, Glycerin, Propylene Glycol, Purified Water

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Warnings

Ask a Doctor before use if you have

eardrainage, discharge, ear pain,irritation

rash in the ear, or are dizzy
injury or perforation (hole) of the ear drum
Recently had ear surgery

Blue EchoCare

Active Ingredient

Carbamide peroxide 6.5%.....Earwax removal aid

Purpose

Use

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

Warnings (For external use only)

Ask a Physician before use if you have • ear drainage or discharge • ear pain, irritation, or rash in the ear • recently had ear surgery • dizziness • an injury or perforation (hole) of the eardrum. When using this product avoid contact with eyes.

Stop use and ask a doctor if • you need to use for more than four days • excessive earwax remains after a four day treatment with this product. **Keep out of the reach of small children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions (FOR USE IN THE EAR ONLY)

Remove hearing aids before use. Adults and children over 12 yrs of age: Tilt head to the side and place 5 to 10 drops into the ear canal • Tip of applicator should not enter into the ear canal • Keep drops in ear for several minutes by keeping head tilted sideways or placing cotton on 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 syringe

Children under 12 yrs of age: Consult a Physician.

Other Information

• Do not store above 82°F (28°C) • Store bottle in outer carton • Product foams on contact with earwax due to the release of oxygen. There may be an associated "crackling" sound. • Keep cap on bottle when not in use

Inactive Ingredients

Citric Acid, Sodium Citrate Dihydrate, Sodium Lauryl Sulfate, Glycerin, Propylene Glycol, Purified Water

CLEANSE RIGHT EAR WAX DROPS

ear wax drops solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73117-111(NDC:15579-840)
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Route of Administration		IRRIGATION		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		CARBAMIDE PEROXIDE	65 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73117-111-05	1 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2022	
2	NDC:73117-111-10	1 mL in 1 KIT; Type 0: Not a Combination Product	09/07/2022	
3	NDC:73117-111-15	1 mL in 1 KIT; Type 0: Not a Combination Product	02/15/2023	
4	NDC:73117-111-70	1 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2023	

Blue EchoCare

Active Ingredient

Carbamide peroxide 6.5%.....Earwax removal aid

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	09/07/2022	

Labeler - Blue Echo Care (117048847)

Establishment

Name	Address	ID/FEI	Business Operations
Blue Echo Care		117048847	relabel(73117-111)

Revised: 2/2024

Blue Echo Care