

HARRIS TEETER EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid
Harris Teeter LLC

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.

Carbamide Peroxide 6.5%

Earwax removal aid

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

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 4 days; if excessive earwax remains after use of this product, consult a doctor

When using this product avoid contact with the eyes. If accidental contact with the eyes occurs, flush your eyes with water and consult a doctor.

If product is swallowed, get medical help or contact a Poison Control Center right away.

FOR IN EAR USE 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, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, tartaric acid.



Earwax Removal Drops

Carbamide Peroxide 6.5%

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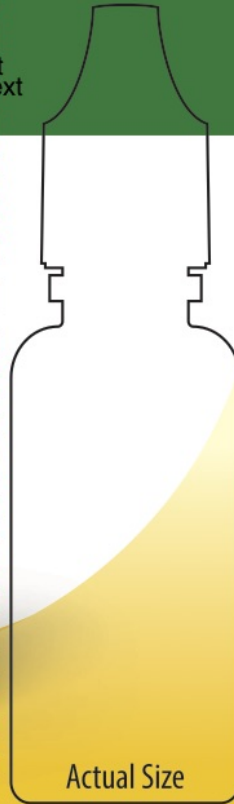
Support your local schools. Together in Education program details available at any Harris Teeter or harristeeter.com.

yourplus guarantee.
If you are not 100% satisfied with this product, simply return it with your VIC card for a full refund. Plus we will replace it with a like item of your choice.
For full details: 1-800-432-6111 or harristeeter.com.

- * Compare to active ingredient in Debrox®
- Safe & Gentle
- Microfoam Cleansing Action
- Easy to Use Instructions



Contents:
0.5 fl oz (15 mL) Drops



Actual Size

Drug Facts

Active ingredient	Purpose
Carbamide Peroxide 6.5%	Earwax removal aid

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

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 ear drum or after ear surgery, unless directed by a doctor
- for more than 4 days; if excessive earwax remains after use of this product, consult a doctor

When using this product • avoid contact with eyes. If accidental contact with eyes occurs, flush eyes with water and consult a doctor

Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away

Directions

FOR IN EAR USE 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

- do not store above 86°F (30°C)
- protect from heat and direct sunlight
- keep cap on bottle when not in use

Inactive ingredients

citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, tartaric acid

*This product is not manufactured or distributed by Prestige Brands Holdings, Inc., owner of the registered trademark Debrox®

PROUDLY DISTRIBUTED BY:
HARRIS TEETER, LLC
MATTHEWS, NC 28105



HARRIS TEETER EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-117
Route of Administration	TOPICAL		

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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

TARTARIC ACID (UNII: W4888I119H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-117-01	1 in 1 CARTON	04/27/2022	
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 final	part344	04/27/2022	

Labeler - Harris Teeter LLC (048463103)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(69256-117)

Revised: 4/2022

Harris Teeter LLC