

EAR DROPS- carbamide peroxide 6.5% liquid

Good Sense

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

Earwax removal aid

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 ear • dizziness • an injury or perforation (hole) of the eardrum • recently had ear surgery

When using this product avoid contact with eyes

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.

Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water

Questions?

1-866-483-2846

Drug Facts (continued)

Other information

- do not store above 86°F (30°C)
- store bottle in the outer carton
- product foams on contact with earwax due to release of oxygen. There may be an associated "crackling" sound.
- keep cap on bottle when not in use

Inactive ingredients Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water.

Questions?
1-866-483-2846

IMPORTANT:
Keep this carton for future reference on full labeling.

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

GOODSENSE®

Non-Irritating

Ear Wax Removal Drops

6.5% Carbamide Peroxide / Ear Wax Removal Aid

- Safe, Gentle, Non-irritating
- Easily Cleanses Ear With Foaming Action

*Compare to active ingredient of Debrox®

100% SATISFACTION GUARANTEED

0.5 FL OZ (15 mL)



ACTUAL SIZE

DO NOT USE IF SAFETY SEAL IS TORN OR MISSING

Drug Facts

Active ingredient	Purpose
Carbamide Peroxide 6.5%.....	Earwax removal aid

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

Warnings

Do not use if you have

- ear drainage or discharge
- irritation or rash in the ear
- an injury or perforation (hole) of the eardrum
- recently had ear surgery
- ear pain
- dizziness

When using this product avoid contact with the eyes

Do not use if

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

Keep this and all drugs 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
- 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 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: consult a doctor

Distributed by: Geiss, Destin & Dunn, Inc.
Peachtree City, GA 30269
www.valuelabels.com
1-866-696-0957

GOODSENSE®
Ear Wax Removal Drops
6.5% Carbamide Peroxide / Ear Wax Removal Aid

EAR DROPS

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-508
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Lauroyl Sarcosinate (UNII: 632GS99618)	
Sodium Stannate (UNII: NJ7C1V83KG)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-508-01	1 in 1 CARTON	09/01/2017	
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	09/01/2017	

Labeler - Good Sense (076059836)

Registrant - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(50804-508) , label(50804-508)

Revised: 8/2018

Good Sense