

EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid
Humco Holding Group, 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.

Private Label Earwax Removal- 0097

Citric Acid

Flavor

Glycerin

Propylene Glycol

Sodium Lauroyl Sarcosinate

Sodium Stannate

Purified Water

Earwax removal aid.

Adults and children over 12 yrs of age: tilt head to the side and place 5 to 10 drops into the ear canal.

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

For External Use Only.

Ask a doctor 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

Carbamide Peroxide 6.5%

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

CVS Label



Earwax Removal Kit

CARBAMIDE PEROXIDE 6.5%

Earwax removal aid

Drug Facts
Active ingredient: Carbamide peroxide 6.5%
Inactive ingredient: Earwax removal aid

Uses
To remove wax in or out of ear, eardrum, eardrum and remove earwax.

Warnings
Do not use if you have ear pain, ear discharge, or ringing in the ear. Do not use if you have a hole in the eardrum or if you have had ear surgery. Do not use if you have a history of ear infections.

Directions
Use as directed. Do not use more than once a day. Do not use for more than 10 days.

Other important information
Keep this and all medicines out of the reach of children. Do not use if you are allergic to any of the ingredients. Do not use if you have a history of ear infections.

Directions
Use as directed. Do not use more than once a day. Do not use for more than 10 days.

Other important information
Keep this and all medicines out of the reach of children. Do not use if you are allergic to any of the ingredients. Do not use if you have a history of ear infections.

The CVS Health Earwax Removal Kit, when used as directed, cleanses the ear with foaming action to provide a safe, non-irritating method of softening and removing earwax. Note: Ear drops will foam on contact with earwax due to the release of oxygen.

CVS Quality
Manufactured by CVS Pharmacy, Inc. One CVS Drive, Woburn, MA 01895. NDC 1333-1000-01. ©2013 CVS Health. All rights reserved.

Actual Size Syringe



Earwax Removal Kit

CARBAMIDE PEROXIDE 6.5%

- Soft, gentle & non-irritating
- Easily cleanses ear with foaming action
- Kit includes soft rubber bulb ear syringe & drops



1 RUBBER BULB SYRINGE & DROPS
0.5 FL. OZ. (15 mL)

PACKAGING INFORMATION
NET CONTENTS: 0.5 FL. OZ. (15 mL)
NDC 1333-1000-01
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OR PHARMACEUTICAL

Actual Size Package Contents

Earwax removal aid
CARBAMIDE PEROXIDE 6.5%
Ear Drops

CVS Health.

CVS Health.

Compare to the active ingredient in Debrox® Ear Drops*

CVS Health.

Ear Drops

CARBAMIDE PEROXIDE 6.5%

Earwax removal aid

- Safe, gentle & non-irritating
- Easily cleanses ear with foaming action

Drug Facts (continued)

Other information

■ do not store above 86°F (30°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, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sarcosinate, Sodium Stannate, Purified Water.

IMPORTANT:

Keep this carton for future reference on full labeling.

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895
© 2019 CVS/pharmacy
CVS.com®
1-800-SHOP CVS
V-13433

 **CVS Quality**
Money Back Guarantee

Actual Bottle
Size on Side Panel

0.5 FL OZ (15 mL)

SEALED FOR YOUR PROTECTION. DO NOT USE IF SHRINK BAND OR BOTTLE IS BROKEN OR MISSING AT TIME OF PURCHASE.

Package Contains
One Bottle

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

For external use only

Ask a doctor 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 the 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 children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

FOR USE IN THE EAR ONLY

Remove any 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 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 yrs of age: Consult a physician.

Continued >

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

FG# 0105A



Earwax Removal Aid
Carbamide Peroxide, 6.5%

Earwax Removal Kit

LEADER

Drug Facts	
Active ingredient Carbamide peroxide 6.5%, for USP <small>Carbamide peroxide 6.5% NADA 141-202 (2012)</small>	Purpose Earwax removal
Use For occasional ear wax to soften, loosen and remove excessive ear wax.	
Warnings Ask a doctor before use if you have: ● ear infection or discharge ● ear pain ● ear surgery or perforation ● eardrum injury or perforation (hole) of the eardrum ● If using this product avoid contact with the ears Stop use and ask a doctor if: ● you need to use for more than 7 days ● you experience pain after a 4 day treatment with this product ● removal of the wax is not complete. If you need medical help or need a Poison Control Center (1-800-525-0235) right away.	
Directions FOR USE IN THE EAR ONLY! Necessarily hearing aids, avoid use	
Read and understand the: ● 2 yrs of age or over. C the side and place 3 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 backward or placing cotton in the ear. ● Use frequently for up to 7 days if needed, or as directed by doctor. ● Dry ear: opening after treatment may be removed by gently flushing the ear with warm water, using a soft tissue with ear syringe	
Caution under 12 years of age: Consult a physician.	
Other information ● Do not use above 30°C (86°F) or store bottle in water container. Contact ears or contact with water due to the release of oxygen. There may be an associated "fizzing" sound. ● Keep cap on bottle when not in use.	
Inactive ingredients Dist. Acid, Fluoride, Glycerin, Polyethylene Glycol, Boric Acid, Salicylic Acid, Sodium Bicarbonate, Sodium Chloride, Purified Water.	
Contains Benzoin & Camphor? 1.800.882.3435	

The earwax removal kit when used as directed, cleanses the ear with foaming action to help soften and remove ear wax.

Note: ear drops will foam on contact with earwax due to the release of oxygen which may cause an associated crackling sound.

The product is not for use in the ear canal or for use in the ear canal.



LEADER

LEADER

Earwax Removal Kit

Carbamide Peroxide, 6.5%
Earwax Removal Aid

SEELED FOR PROTECTION
DETECTED IF
SERIAL LEAD
INTEGRITY IS
BROKEN
OR WAXING
AT THE TIME OF
PURCHASE.



Earwax Removal Aid
Safe & Gentle
Foaming Cleansing Action
Kit includes Soft Rubber
Bulb Ear Syringe & Drops

COMPARE TO
DEB-ROX
EAR DROPS
active ingredient "it"

100% Money Back Guarantee

1 RUBBER BULB SYRINGE
0.5 FL OZ (15 ML) DROPS

© 2012 Cardinal Health. All rights reserved. 02894, 0291.
Includes: DeB-Rox, 0.5 FL OZ, and Rubber Bulb Ear
Syringe. A registered trademark of Cardinal Health. All
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INCORPORATED
3030 N. AUSTIN
BLVD
ANN ARBOR MI 48106-4211
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100% Money Back Guarantee
Return to pack if purchase is not satisfied

CIN 100000 REV. 4/11
0 92295 13753 C
R 0301 US

Reduced to

SEAL IS FOR YOUR PROTECTION. DO NOT USE IF SPRINKLER OR BOTTLE IS DAMAGED OR MISSING AT TIME OF PURCHASE.

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:
For external use only.
Ask a doctor before use if you have:
• ear drainage or discharge
• ear pain, infection, or noise in the ear
• recently had ear surgery
• diabetes
• an injury or perforation (hole) in the eardrum.

When using this product avoid contact with the eyes.
Stop use and ask a doctor if:
• you need to use for more than four days
• excessive earwax remains after a use
• you feel burning or stinging.

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!
Remove any existing eardrops.
Adults and children over 12 years of age: 10 drops in the side ear twice a day for 10 days into the ear canal.

To get applicator to enter into the ear canal:
• Keep steps in ear for several minutes by keeping head tilted straight or placing cotton in the ear.

• Use twice daily for up to 4 days if needed, or as directed by a doctor.
• Any new remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe.

Children under 12 yrs of age: Consult a physician.

Contains 1.5

*This product is not manufactured or distributed by Pharmacia-Elmids Inc., owner of the registered trademark OTCare®.
DISTRIBUTED BY: RITE-aid, INC.
SCHLITZ LANE, CHICAGO, ILL. 60601
www.riteaid.com

(Drug Facts continued)

Other information:
• do not store above 77°F (25°C)
• store bottle in outer carton
• protect flame on contact with wax due to the release of oxygen.
There may be an associated "crackling" sound.
• keep cap on bottle when not in use.

Inactive ingredients:
Dibutyl, Flavor, Glycerin, Polyethylene Glycol, Sodium Lactate, Sorbitan, Sodium Stearoyl Sulfonate, Purified Water.

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

SATISFACTION GUARANTEE:
If you're not satisfied, we'll happily refund your money.

ACTUAL SIZE BOTTLE



EARWAX REMOVAL DROPS

carbamide peroxide 6.5%

Compare to the active ingredient in Debrox® Ear Drops*

EARWAX REMOVAL DROPS

carbamide peroxide 6.5%

safe, gentle, non-irritating
easily cleanses ear with microfoam action



PHARMACY

0.5 FL OZ (15 mL)

Major Label

MAJOR[®]

Ear Drops

Carbamide Peroxide 6.5%
Non USP^{*}

MAJOR[®]

NDC 0395-9133

Carbamide is the active ingredient in Debrox Ear Drops[®]

SEALED FOR YOUR PROTECTION. DO NOT USE IF SHRINKBAND ON BOTTLE IS BROKEN OR MISSING AT TIME OF PURCHASE.

Ear Drops

Carbamide Peroxide

6.5%

Non USP^{*}

Earwax removal aid

- Safe, gentle, and non-irritating
- Easily cleans ear with foaming action

0.5 FL OZ (15 mL)

Actual Size Bottle

Drug Facts	
Active Ingredient	Purpose
Carbamide peroxide 6.5% non USP [*] Earwax removal aid *differs from USP specifications	
Use: For occasional use as an aid to soften, loosen and remove excessive earwax.	
Warnings	
For external use only	
Ask a doctor 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 the 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 reach of children. If swallowed, get medical help or contact a Poison Control Center 1-800-222-1222 immediately.	
Directions	
FOR USE IN THE EAR ONLY	
Remove any 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 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 yrs of age: Consult a physician. Caution:	

Drug Facts (continued)	
Other information	
• do not store above 86°F (30°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, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sulfonate, Sodium Stannate, Purified Water.	
Questions or Comments?	
(800) 515-2471	

IMPORTANT
Keep this carton for future reference on full labeling.

Distributed by:
MAJOR[®]
PHARMACEUTICALS
37177 N Laurel Park Dr.
Suite 230
Livonia, MI 48150

Rev. 12/19 M-74
Re-order No. 701036



EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-9133
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	0.065 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM STANNATE (UNII: NJ7C1V83KG)	

SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9133-90	1 in 1 CARTON	06/04/2019	
1		15 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0395-9133-45	1 in 1 CARTON	06/04/2019	
2		15 mL in 1 BOTTLE, DROPPER; 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	06/04/2019	

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Humco Holding Group, Inc (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc		825672884	manufacture(0395-9133) , analysis(0395-9133) , pack(0395-9133) , label(0395-9133)

Revised: 6/2020

Humco Holding Group, Inc