

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

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	Regulate
Active ingredient	Carbamide peroxide 6.5% Earwax removal aid
Other ingredients	Water
Uses	To remove ear wax or ear infections, earaches, and earwax irritation.
Warnings	Do not use if you have a perforated eardrum or ear infection. Do not use if you have a drainage tube in your ear. Do not use if you have a history of ear surgery. Do not use if you have a history of ear surgery. Do not use if you have a history of ear surgery.
Directions	Use as directed. Do not use more than once a day. Do not use for more than 30 days.
Other important information	Keep out of reach of children. If you are pregnant, call your doctor before use.
Keep out of reach of children	Keep out of reach of children. If you are pregnant, call your doctor before use.
Store at room temperature	Store at room temperature. Do not use if the seal is broken.
Contains 1.02 FL OZ (30 mL)	Contains 1.02 FL OZ (30 mL)

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.

Developed by CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02896
CVS/LEO[®] - 400-999-0000
U.S. Patent 6,484,443

IMPORTANT: Read the carton for future reference on full labeling.

Actual Size



Complete & active ingredients in delivery ear drops



Earwax Removal Kit

CARBAMIDE PEROXIDE 6.5%

Earwax removal aid

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



Actual Product Size as Seen on Shelf

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

PACKED FOR YOU
WITH PREVIOUSLY USED KIT
IN ORIGINAL RETAIL BOX
OR REPACKAGE.

Package Contains One Bottle Actual Size

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



KO B

LEADER²

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal Aid

Drug Facts

Active ingredient	Purpose
Carbamide peroxide 6.5% non USP* ...Earwax removal aid *pH differs from USP specifications	

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

Warnings

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 (1-800-222-1222) 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® Ear Drops.

Drug Facts (continued)

Other information

■ do not store above 25°C (77°F) ■ 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 Lauroyl Sarcosinate, Sodium Stannate, Purified Water

Questions & comments?

1-800-200-6313

IMPORTANT

Keep this carton for future reference on full labeling.

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DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

100% Money Back Guarantee
Return to place of purchase if not satisfied.

LEADER²

NDC 70000-0490-1

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal Aid

Earwax Removal Aid

Safe & Gentle

Foaming
Cleansing
Action

COMPARE TO
DEBROX[®]
EAR DROPS
active ingredient*

100% Money
Back Guarantee

0.5 FL OZ (15 mL)

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



KO B

SFRA_04043 045220017-001

KO B

KO B

CIN 5511647 REV. 3/22



R 02/18/22

SEAL IS YOUR PROTECTION. DO NOT USE IF SEALING IS BROKEN OR MISSING AT TIME OF PURCHASE.

Use with caution.

Keep this and all other medicines out of the reach of children.



Drug Facts

Active ingredient: Carbamide Peroxide 6.5%
Proprietary: Carbamide Peroxide 6.5% (OTC), Earwax Removal Solution (OTC), Carbamide Peroxide 6.5% (OTC)

Use: For earwax removal. Use in ear to soften, break up and remove earwax.

Warnings:

Ask a doctor before use if you have: ear drainage or discharge, ear pain, infection or rash in the ear, recently ear ear surgery, ear tubes, or an injury or perforated eardrum.

When using this product avoid contact with eyes. Stop use and consult a doctor if you need to use for more than two weeks, a excessive earwax, or if you experience a burning, stinging or itching.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-527-0899) right away.

Directions:

FOR USE IN THE EAR ONLY
Remove any hearing aids before use.
Adults and children over 6 years of age: tilt head to the affected side 2 to 30 days into the ear canal.
• To get solution inside ear, tilt head to ear canal.
• Gently massage the ear for several minutes by applying firm, slow strokes or gentle circles to the ear.
• Use twice daily for up to 4 days if needed, or as directed by a doctor.
• If you are wearing the hearing aid, remove it before using the solution.
• Use with warm water. Using cold water will not help.
Children under 6: use as age. Consult a physician.

Continued

This product is a combination of Carbamide Peroxide 6.5% (OTC), Earwax Removal Solution (OTC), Carbamide Peroxide 6.5% (OTC)

Drug Facts (continued)

Other information:

• Do not store above 25°C (77°F).
• Store bottle in your car or pocket when you are on the go.
• Do not use if you have ear pain, infection or rash in the ear.
• Do not use if you have recently had ear surgery or ear tubes.
• Do not use if you have a perforated eardrum.

Inactive ingredients:

Carbamide Peroxide 6.5%, Carbamide Peroxide 6.5% (OTC), Carbamide Peroxide 6.5% (OTC), Carbamide Peroxide 6.5% (OTC), Carbamide Peroxide 6.5% (OTC), Carbamide Peroxide 6.5% (OTC)

IMPORTANT:

Keep this carton for future reference or for labeling.

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85788000 CARBAMIDE PEROXIDE 6.5% (OTC) 0.5 FL OZ (15 mL)

100% Power. Each Guarantee. Return to manufacturer if not satisfied.



Rite Aid Label

CARBAMIDE PEROXIDE 6.5%
safe, gentle, non-irritating
easily cleanses ear with
microfoam action

EARWAX REMOVAL KIT

DO NOT USE IF TAMPER EVIDENT SHRINKBAND
ON BOTTLE IS BROKEN OR MISSING.

Drug Facts	
Active ingredient Carbamide peroxide 6.5%	Purpose Earwax removal aid
Use For occasional use as an aid to soften, loosen and remove excessive earwax.	
Warnings Do not use if: If you have ear drainage or discharge, ear pain, infection, or tinnitus in the ear or are dizzy, consult a doctor. If you have an injury or perforation (hole) of the ear or other ear surgery, unless directed by a doctor. For more than 4 consecutive 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 eyes occurs, flush eyes with water and consult a doctor. Stop use and ask a doctor if: Excessive earwax remains after use of this product for 4 consecutive days.	
Keep out of the reach of children. If removed, get medical help or contact a Poison Control Center right away.	
Directions FOR USE IN THE EAR ONLY. Adults and children over 12 yrs of age: With head sideways and place 5 to 10 drops into the 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 the 4-day treatment may be removed by gently flushing between with warm (body temperature) water, using a soft rubber bulb ear syringe. Children under 12 yrs of age: Consult a physician.	
Other information Protect from heat and direct sunlight. Keep cap on bottle when not in use.	
Inactive ingredients citric acid, flavor, glycerin, propylene glycol, sodium lauryl sarcosinate, sodium stannate, purified water	

ACTUAL SIZE



DROPS
EASY TO APPLY



EAR WASHER
EASY TO USE

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

FREE FROM GLUTEN FREE

Compare to the active ingredient in Debrox® Ear Drops®

NDC 11822-30711-7

EARWAX REMOVAL KIT

CARBAMIDE PEROXIDE 6.5%

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

kit includes:
ear drops
& washer



0.5 FL OZ (15 mL)

EARWAX REMOVAL KIT

CARBAMIDE PEROXIDE 6.5%
safe, gentle, non-irritating
easily cleanses ear with
microfoam action

OUR PROMISE:

Responsibly Sourced

Tree Free

IMPORTANT
Keep this carton for future
reference on full labeling.

DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE
CRANFILL, PA 17011
www.riteaid.com

**SATISFACTION
GUARANTEE**
If you're not satisfied, we'll
happily refund your money!



0 11822 30711 6

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 rash in the ear; recent facial ear surgery; diabetes; or 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; or 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 existing wax before use.

Adults and children over 12 years of age: tilt head to the side and place 5 to 10 drops into the ear canal.
To let applicator droplet softener 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

(Drug Facts continued)

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

Inactive ingredients:
Dibutyl Tinol, Flavor, Glycerin, Polyethylene Glycol, Sodium Lactate, Sorbitan, Sodium Borate, Purified Water.

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

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

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 to active ingredient in Debrox Ear Drops[®]

SEALED FOR YOUR PROTECTION. DO NOT USE IF SHRINKBAR 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 Carbamide peroxide 6.5% non USP^{*} Earwax removal aid (all differs from USP specifications)

Purpose 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 discharges • 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 233
Livonia, MI 48152

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: 059QF0KO0R)	

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 Drug	M014	06/04/2019	

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-9133) , analysis(0395-9133) , pack(0395-9133) , label(0395-9133)

Revised: 12/2023

Humco Holding Group, Inc