

EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid
Pharma Nobis, LLC

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	Warnings
Active ingredient: Carbamide Peroxide 6.5%	Do not use if you have: • a known allergy to any of the ingredients • a perforated eardrum • ear pain • ear discharge • ear infection • ear surgery • ear tubes
Other ingredients: Distilled water	Use: • Apply to the ear canal. Do not use more than 1 drop at a time. Do not use more than 3 times a day.
Directions: Insert the nozzle into the ear canal and gently squeeze the bulb. Do not use more than 1 drop at a time. Do not use more than 3 times a day.	Keep out of reach of children.
Warnings: • Do not use if you have a known allergy to any of the ingredients • Do not use if you have a perforated eardrum • Do not use if you have ear pain • Do not use if you have ear discharge • Do not use if you have an ear infection • Do not use if you have had ear surgery • Do not use if you have ear tubes	Caution: Use only as directed. Do not use more than 1 drop at a time. Do not use more than 3 times a day.
Other information: This product is not intended for use in children under 6 years of age. For use in children, consult your doctor.	Keep out of reach of children.
Questions or concerns about directions for use or these ingredients? Call a pharmacist for more information.	Keep out of reach of children.

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.

This product is not intended for use in children under 6 years of age. For use in children, consult your doctor.

© 2014 CVS Health. All rights reserved.

Distributed by: CVS Pharmacy, Inc.
 One CVS Drive, Weymouth, MA 02098
 CVS Health™ - 1-800-Call-CVS
 U.S. Patent Nos. 7,510,173

CVS Quality
 Helping You Live Better

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

Actual Size
 Syringe



Compare to other ingredients in other 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



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

Actual Product Size
 as Shown

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



LEADER²

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal AidLEADER²

NDC 7000-0490-1

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal Aid

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



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 "cracking" sound ■ keep cap on bottle when not in use

Inactive ingredients

Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sarcosinate, Sodium Stearate, Purified Water

Questions & comments?

1-800-423-6867

IMPORTANT

Keep this carton for future reference on full labeling.

©2022 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43007**100% Money Back Guarantee**
Return to place of purchase if not satisfied.Earwax Removal Aid
Safe & GentleFoaming
Cleansing
ActionCOMPARE TO
DEBROX[®]
EAR DROPS
active ingredient^{*}100% Money
Back Guarantee

0.5 FL OZ (15 mL)

CIN 5511647 REV. 6/22



12

LEADER²

NDC 70000-0490-1

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal Aid

Safe & Gentle
Foaming Cleansing
Action

0.5 FL OZ (15 mL)

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

Drug Facts	Purpose
Active ingredient 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.	
Inactive ingredients Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sarcosinate, Sodium Stannate, Purified Water.	
Questions & comments? 1-800-423-6967	
RETAIN OUTER CARTON FOR FULL LABELING.	

DIST. BY CAH DUBLIN OH, 43017 ©2022 Cardinal Health R 02/18/22
1-800-200-6315

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

CIN 5511647 REV. 6/22

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.

©2022 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

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

Earwax Removal Kit

Carbamide Peroxide, 6.5%

LEADER

Drug Facts

Active ingredient	Purpose
Carbamide peroxide (6.5% for USP) Earwax removal aid	Earwax removal aid

Use: For occasional earwax buildup, loosen and remove excessive earwax.

Warnings:
 • Ask a doctor before use if you have: • ear infection or discharge • ear pain, ringing or fullness • ear surgery or perforated eardrum • history of ear surgery • diabetes • history or perforation (hole) of the eardrum
 • Stop using this product until contact with the ears

Stop use and ask a doctor if: • you need to use for more than 10 days • necessary earwax removal after a 4-day treatment with this product
 • removal of the wax is not complete. If unresolved, get medical help or contact a Poison Control Center (1-800-525-0243) right away.

Directions:
 For use in the ear only.
 Recommended: Insert into ear canal.

Adult and children over 2: • Use of age 18 level. • The side and place to use. • Drop into the ear canal. • Tip of applicator should rest on the ear canal. • Keep drops in ear for several minutes by keeping head tilted downward or placing cotton in the ear. • Use frequently for up to 10 days if needed, or as directed by doctor. • Dry ear, opening after treatment may be relieved by gently flushing the ear with warm water, using a soft rubber bulb ear syringe.

Children under 2 years of age: Consult a physician.

Other information:
 • Do not use above 37°C (99°F) or store bottle in water container. Contact with water 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:
 Citric Acid, Flavors, Glycerin, Polyethylene Glycol, Sodium Lauryl Sulfonate, Sodium Sulfate, Purified Water.

Contains Benzocaine?
 1-800-885-3435

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

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

The product listed here is not intended to be used in the ear.



NDC 5985-988-1

Earwax Removal Kit

Carbamide Peroxide, 6.5%
Earwax Removal Aid

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

COMPARE TO DEB-ROX EAR DROPS
 Active Ingredient #1*

100% Money Back Guarantee

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

SEALING FOR PROTECTION OF SOFT RUBBER BULB SYRINGE OR BOTTLE AT TIME OF PURCHASE.

Actual Size

©2011 Cardinal Health. All rights reserved. OTCMA, 08/11. Includes: DEB-ROX, DEB-ROX Earwax Removal Aid. *Active ingredient as determined by Cardinal Health. All trademarks are property of their respective owners.

Cardinal Health
 SCRIBNER DRIVE
 BURLINGTON, NJ 08016
 1-800-525-0243
 Dated 12/11/11

100% Money Back Guarantee
 Return to pack or purchase if not satisfied



Reduced to

SEALED FOR YOUR PROTECTION. DO NOT USE IF SWIMMING EARPLUGS ARE IN PLACE AT TIME OF POURING.

VOID WITH

VOID WITH



Drug Facts

Active ingredient: Carbamide Peroxide 6.5%
 Cetastrol HCL 0.1%
 Cetastrol HCL 0.1%
 Cetastrol HCL 0.1%

Use: For earwax removal. Do not use if you have ear pain, ear infection, or ear surgery. Do not use if you have a perforated eardrum.

Warnings:

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

When using this product avoid contact with eyes. Stay out of contact. Avoid contact with eyes. Wash hands for 20 seconds before and after use. Avoid contact with eyes.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-525-0247) right away.

Directions:

FOR USE IN THE EAR ONLY

Remove any hearing aids before use.

Adults and children over 12 years of age: tilt head to the affected side 2 to 30 days into the ear canal.

• To get earwax out, tilt head to the affected side.

• Gently massage the ear for several minutes by applying pressure to the side of the head.

• Use head daily for up to 4 days if needed, or as directed by a doctor. If you have hearing after treatment, you may have earwax buildup. If you do not, you may have earwax buildup. If you do not, you may have earwax buildup.

• Do not use if you have ear pain, ear infection, or ear surgery.

• Do not use if you have a perforated eardrum.

• Do not use if you have ear tubes.

• Do not use if you have ear surgery.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

Drug Facts (continued)

Other information:

• Do not store above 25°C (77°F). See USP Controlled Room Temperature. Excursions permitted to 15°C to 30°C (59°F to 86°F) are allowed.

• Do not use if you have ear pain, ear infection, or ear surgery.

• Do not use if you have a perforated eardrum.

• Do not use if you have ear tubes.

• Do not use if you have ear surgery.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

• Do not use if you have earwax buildup.

LEADER
Earwax Removal Drops
 Carbamide Peroxide, 6.5%
 Earwax Removal Aid

LEADER
 NDC 1084-0081
Earwax Removal Drops
 Carbamide Peroxide, 6.5%
 Earwax Removal Aid

Earwax Removal Aid
 Safe & Gentle
 Foaming Cleansing Action

COMPARE TO
 DEBROCK
 EAR DROPS
 active ingredient

100% Foamy
 Soft Cleansing

0.5 FL OZ (15 mL)

CH 6 917647 REV. 2/18
 96295 13704
 R 300118

Rite Aid Label

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 or after 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

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®.

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

(Drug Facts continued)**Other information**

■ do not store above 77°F (25°C) ■ store bottle in outer carton ■ product foams on contact with earwax due to the release of oxygen. There may be an associated "cracking" 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.

SATISFACTION GUARANTEE:

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

EARWAX REMOVAL DROPS

carbamide peroxide 6.5%

Compare to the active ingredient in **Debrox® Ear Drops***

FREE | **GLUTEN FREE**
F R M

EARWAX REMOVAL DROPS

carbamide peroxide 6.5%

safe, gentle,
non-irritating

easily cleanses ear
with microfoam action



0.5 FL OZ (15 mL)

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



ACTUAL SIZE BOTTLE



EARWAX REMOVAL DROPS

carbamide peroxide 6.5%



0.5 FL OZ (15 mL)

DO NOT USE IF SHRINK BAND ON BOTTLE IS BROKEN OR MISSING.

Drug Facts

Active ingredient

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 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.

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

RETAIN OUTER CARTON FOR FULL LABELING.

DISTRIBUTED BY: RITE AID, 200 NEWBERRY COMMONS, ETTES, PA 17319 www.riteaid.com R122022

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		Purpose
Active ingredient	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 or after 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 swallowed, 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: tilt 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 the ear 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
CAMP HILL, PA 17011
www.riteaid.com

SATISFACTION GUARANTEE

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



0 11822 30711 6

OTC PRESCRIPTION INFORMATION
 Read the entire instruction booklet
 before you use this product.
 OTC PRESCRIPTION INFORMATION
 Read the entire instruction booklet
 before you use this product.

EARWAX REMOVAL KIT

OTC PRESCRIPTION INFORMATION
 Read the entire instruction booklet
 before you use this product.

Drug Facts

Read the entire instruction booklet before you use this product. Keep this information with the product. This information does not take the place of reading the label on the medicine. This information does not take the place of reading the label on the medicine.

Warnings:
 Do not use if you are pregnant, breastfeeding, or taking medicine for your heart, blood pressure, or diabetes. Do not use if you are taking medicine for your heart, blood pressure, or diabetes. Do not use if you are taking medicine for your heart, blood pressure, or diabetes.

Directions:
 Use as directed. Do not use more than once a day. Do not use more than once a day. Do not use more than once a day.

Other information:
 This product is not intended to be used as a substitute for medical advice from your doctor. This product is not intended to be used as a substitute for medical advice from your doctor.

ACTUAL SIZE

Compare to the active ingredients in Debrox® Ear Drops*



DROPS
EASY TO APPLY



EAR WASHER
EASY TO USE

*This product is not intended to be used as a substitute for medical advice from your doctor. This product is not intended to be used as a substitute for medical advice from your doctor.

EARWAX REMOVAL KIT

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

IMPORTANT:
 Stop this product for factors
 mentioned in full labeling.

DISTRIBUTED BY:
 BPC INC., 27141 17TH AVE
 COMMERCE, CA 92521
 www.riteaid.com

**SATISFACTION
 GUARANTEED**
 If you are not satisfied with
 your purchase, please return it.

REDUCED TO 60%



0 1822 507 11 4

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; 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.

Be sure to be reach of children if resealed, 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: 1) Insert the white ear applicator 5 to 10 steps into the ear canal. 2) To let applicator slowly and gently enter into the ear canal. 3) Keep steps in ear for several minutes by keeping head tilted straight or placing cotton in the ear. 4) Use twice daily for up to 4 days if needed, or as directed by a doctor. 5) 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.

(Drug Facts continued)

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

Inactive ingredients:
Dibutyl Tin, Flavor, Glycerin, Polyethylene Glycol, Sodium Lauryl Sulfonate, Sodium Borate, Purified Water.

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

ACTUAL SIZE BOTTLE

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

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



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

RITE AID PHARMACY 0.5 FL OZ (15 mL)

Major Label

MAJOR[®]

Ear Drops

Carbamide Peroxide 6.5%
Non USP^{*}

MAJOR[®]

NDC 0514-853-35

Carbamide to 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 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?	
800-815-2471	

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:82645-910
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:82645-910-90	1 in 1 CARTON	06/04/2019	
1		15 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:82645-910-45	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 - Pharma Nobis, LLC (118564114)

Registrant - Pharma Nobis, LLC (118564114)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(82645-910) , analysis(82645-910) , pack(82645-910) , label(82645-910)