

LEADER EARWAX REMOVAL KIT- carbamide peroxide 6.50% kit liquid
Cardinal Health, 110 dba Leader

LEADER Earwax Removal Kit

Carbamide Peroxide 6.5% non USP*

*pH differs from USP specifications

Earwax removal aid

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

Ask a doctor before use if you have:

ear drainage or discharge

ear pain, irritation, or rash in ear

recently had ear surgery

dizziness

an injury or perforation of the eardrum

Citric acid

Flavor

Glycerin

Propylene glycol

Sodium Lauroyl Sarcosinate

Sodium Stannate

Purified water

- 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 ear with warm water, using a soft rubber bulb ear syringe

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

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.

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DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017**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_{TM}

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	

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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

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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

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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

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KO B

KO B

CIN 5511647 REV. 3/22



0 96295 13704 0
R 02/18/22

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



Drug Facts

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

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Children under 12 yrs of age: Consult a physician
Continued >

*This product is not intended to be used in conjunction with any other ear wax removal product.

Drug Facts (continued)

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

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

Questions & comments?
1-800-662-3435

IMPORTANT
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DISTRIBUTED BY CARDINAL HEALTH
CURLAND, OHIO 43017

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

LEADER

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal Aid

LEADER

NDC 70008-0490-1

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*

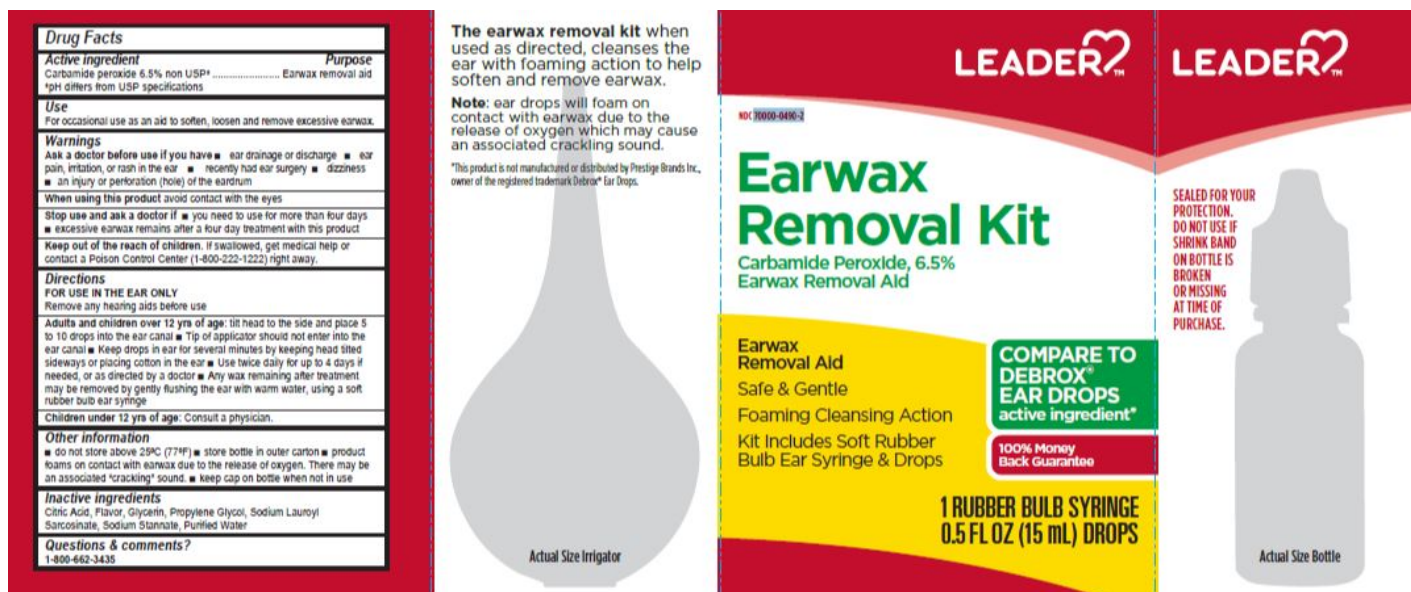
0.5 FL OZ (15 mL)

Special Coating Knockout

CIN 55116-47 REV. 2/19



R 02/01/19



LEADER EARWAX REMOVAL KIT

carbamide peroxide 6.50% kit liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0490
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
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM STANNATE (UNII: NJ7C1V83KG)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0490-2	15 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/06/2019	
2	NDC:70000-0490-1	1 in 1 CARTON	05/06/2019	

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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	05/06/2019	

Labeler - Cardinal Health, 110 dba Leader (063997360)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	pack(70000-0490) , label(70000-0490) , manufacture(70000-0490) , analysis(70000-0490)

Revised: 12/2023

Cardinal Health, 110 dba Leader