

WALGREENS EAR WAX REMOVER- carbamide peroxide 6.5% liquid
Walgreens Company

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.

Walgreens Ear Wax Remover

Active ingredient

Carbamide Peroxide 6.5%

Purpose

Ear Wax Removal Aid

Uses

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

Warnings

Ask a Doctor before use if you have

- eardrainage, discharge, ear pain,irritation
- rash in the ear,or are dizzy
- injury or perforation (hole) of the ear drum
- Recently had ear surgery

Stop Use and ask a Doctor if

- you need to use for more than 4 days
- excessive ear wax remain after use of this product

When using this product

do not use for more than four days

avoid contact with the eyes. If accidental contact with the eyes occurs, flush eyes with water and consult a doctor

if excessive earwax remains after the use of this product, consult a doctor

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 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 earwax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe.
- When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal.

Children under 12 years: consult a doctor.

Inactive Ingredients

Citric Acid, Glycerin, Propylene Glycol, Sodium Citrate, Sodium Lauryl Sulfate, Tartaric Acid

Other information

Protect from heat and direct sunlight

product foams on contact with ear wax due to release of oxygen, there may be associated cracking

Keep cap on bottle when not in use.

Lot No. and EXP date: see label, bottom container or box.

Principal Display Panel Bottle Label 0.5 FL OZ

Walgreens Ear Wax Remover NDC 0363-2068-15

Ear Wax Removal drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15ml)

ACTIVE INGREDIENT: Carbamide peroxide, 6.5% **USES:** For occasional use as an aid to soften, loosen and remove excessive ear wax. **WARNINGS:** Ask a doctor if you have ear drainage or discharge, ear pain, irritation or rash in the ear, dizziness, had an injury or perforation (hole) of the ear drum or recently had ear surgery. Stop use and ask a doctor if you need to use for more than 4 days or if excessive ear wax remains after use of the product. When using this product, do not get into eyes. **Keep out of reach of children.** In case of accidental overdose or allergic reaction, get medical help or contact a Poison Control Center immediately.

Walgreens Pharmacist Recommended
Our pharmacists recommend the Walgreens brand.
We invite you to compare to national brands.

ITEM 157161 W00000-0000-0 W3ORG0721-F

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Ear Wax Removal Drops

CARBAMIDE PEROXIDE 6.5%

Non-Irritating

- Safe, gentle, non-irritating
- Easily cleanses ear

0.5 FL OZ (15 mL)

DIRECTIONS: FOR IN EAR USE ONLY. Adults and children over the age of 12 years: Tilt head sideways and place 5-10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in for several minutes by keeping your head tilted or placing cotton in your ear. Use twice daily 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.

OTHER INFORMATION: Avoid exposing bottle to excessive heat or direct sunlight. Product foams on contact with ear wax due to release of oxygen. Keep cap on bottle when not in use.

INACTIVE INGREDIENTS: See carton.

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

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MADE IN U.S.A. OF U.S. AND IMPORTED
INGREDIENTS AND COMPONENTS

Principal Display Panel Carton Label 0.5 FL OZ

Walgreens Ear Wax Remover NDC 0363-2068-15

Ear Wax Removal drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15ml)

Ear Wax Removal Drops

Walgreens

DO NOT USE IF SAFETY SEAL IS BROKEN 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 ear wax.

Warnings

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- you need to use for more than 4 days
- excessive ear wax remains after use of this product

When using this product do not get into eyes

Keep out of reach of children. In case of accidental overdose or allergic reaction, get medical help or contact a Poison Control Center immediately.

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: consult a doctor

Walgreens Pharmacist Recommended. Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

Drug Facts (continued)

Other information

- Avoid exposing bottle to excessive heat and direct sunlight
- Product foams on contact with earwax due to release of oxygen. There may be an associated cracking
- Keep cap on bottle when not in use
- Lot no. and exp. date: see label, bottom container or box.

Inactive ingredients

- Anhydrous Glycerin, Citric Acid, Propylene Glycol, Sodium Citrate, Sodium Lauryl Sulfate, Tartaric Acid

Questions or comments?

1-800-222-1087



Walgreens

Compare to the active ingredient in Debrox[®]

Ear Wax Removal Drops

CARBAMIDE PEROXIDE 6.5%

Non-Irritating

- Safe, gentle, non-irritating
- Easily cleanses ear



0.5 FL OZ (15 mL)

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

DISTRIBUTED BY:
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200 WILMOT RD.,
DEERFIELD, IL 60015
100% SATISFACTION
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MADE IN U.S.A. OF
INGREDIENTS AND
COMPONENTS

ITEM 157161 W00000-0000-0



W3ORG0821-F

Principal Display Panel Kit Label 0.5 FL OZ

Walgreens Ear Wax Remover Kit NDC 0363-2068-25

Ear Wax Removal drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15ml)



WALGREENS EAR WAX REMOVER

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-2068
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
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TARTARIC ACID (UNII: W4888I119H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-2068-15	1 in 1 CARTON	04/28/2014	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0363-2068-25	1 in 1 KIT	04/28/2014	
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	04/28/2014	

Labeler - Walgreens Company (008965063)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(0363-2068)

Revised: 1/2022

Walgreens Company