

**WAXRX EAR WAX REMOVAL AID DROPS- carbamide peroxide liquid
DOCTOR EASY MEDICAL PRODUCTS, LLC**

Carbamide Peroxide 6.5%

Carbamide Peroxide 6.5%.....Earwax Removal Aid

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

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

FOR USE IN THE EAR ONLY

Adults and children over 12 years of age. Tilt head sideways and place 5-10 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 ears. Flush ear with VERY WARM (body temperature) water using the Wax-Rx Ear Washer.

Children under 12, consult a physician. Drops may be used twice daily for up to 4 days or as directed by a physician.

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

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

WaxRx

EAR WAX

REMOVAL

AID DROPS

6.5% Carbamide Peroxide

Safe, Fast Acting

Alcohol Free

0.5 FL OZ (15 ML)

NOT LABELED FOR INDIVIDUAL SALE.

DO NOT USE IF TAMPER EVIDENT SHRINK FILM IS BROKEN OR MISSING. USE ONLY AS DIRECTED. SEE OUTER BOX FOR COMPLETE DRUG FACTS.

WARNINGS: DO NOT USE IF YOU HAVE DRAINAGE OR DISCHARGE, EAR PAIN, IRRITATION, OR RASH IN THE EAR OR ARE DIZZY. CONSULT A DOCTOR. DO NOT USE IF YOU HAVE ANY PERFORATION (HOLE) OF THE EARDRUM OR AFTER EAR SURGERY UNLESS DIRECTED BY A DOCTOR. DO NOT USE FOR MORE THAN FOUR DAYS. IF EXCESSIVE EAR WAX REMAINS AFTER USE OF THIS PRODUCT, CONSULT A DOCTOR.

CAUTIONS: AVOID EXPOSING BOTTLE TO EXCESSIVE HEAT AND DIRECT SUNLIGHT. KEEP CAP ON BOTTLE WHEN NOT IN USE. AVOID CONTACT WITH EYES. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER.

WaxoRx™
EAR WAX REMOVAL AID DROPS

6.5 % CARBAMIDE PEROXIDE

**Safe, Fast Acting
Alcohol Free**

0.5 FL OZ (15 ML)

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. FLUSH EAR WITH WARM (BODY TEMPERATURE) WATER USING THE WAX-RX EAR WASHER. CHILDREN UNDER 12, CONSULT A PHYSICIAN. DROPS MAY BE USED TWICE A DAY FOR UP TO 4 DAYS OR AS DIRECTED BY A PHYSICIAN.

ACTIVE INGREDIENTS: CARBAMIDE PEROXIDE 6.5%W/W
PURPOSE: EAR WAX REMOVAL
INACTIVE INGREDIENTS: CITRIC ACID, GLYCERIN, PROPYLENE GLYCOL, SODIUM CITRATE, SODIUM LAURYL SULFATE, TARTARIC ACID

NOTE: WAX-RX EAR WAX REMOVAL DROPS WILL FOAM ON CONTACT WITH EAR WAX DUE TO THE RELEASE OF OXYGEN. ALSO, HEATING BEFORE USE IS NOT RECOMMENDED.

Distributed by
Doctor Easy Medical Products LLC
2816 Othos Cv
Orange Park, FL 32065

WAXRX EAR WAX REMOVAL AID DROPS

carbamide peroxide liquid

Product Information

| | | | |
|--------------------------------|------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72724-001 |
| 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 |
|---|----------|
| TARTARIC ACID (UNII: W4888I119H) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72724-001-15 | 15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 12/12/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M014 | 12/12/2018 | |

Labeler - DOCTOR EASY MEDICAL PRODUCTS, LLC (848752523)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------|
| Sheffield Pharmaceuticals LLC | | 151177797 | manufacture(72724-001) |

Revised: 5/2025

DOCTOR EASY MEDICAL PRODUCTS, LLC