EAR WAX REMOVAL DROPS- carbamide peroxide - 6.5% solution/drops Preferred Pharmaceuticals, Inc.

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.

Drug Facts

Active ingredient

Carbamide Peroxide, 6.5%

Earwax removal aid

Uses

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

□ Warnings

Do not use if you have

- eardrainage, discharge, ear pain,irritation
- rashin the ear,or are dizzy
- injuryor perforation (hole) of the ear drum or after ear surgery

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

IKeep 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 agell:**
- 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.

Other information

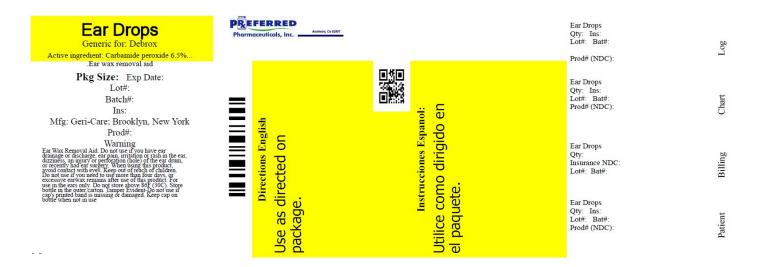
- Protect from heat and direct sunlight
- Keep cap on bottle when not in use.
- Lot No. and EXP date: see label, bottom container or box.
 NDC 68788-7496-01 1 Bottle .5FL OZ

Relabeled by Preferred Pharmaceuticals, Inc.

Inactive ingredients

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

Principal Display Panel Bottle Label 0.5 FL OZ



Preferred Plus Pharmacy Ear Wax Removal drops

Carbamide Peroxide 6.5% 0.5 FL OZ (15ml)

NDC: 68788-7498-01 Bottle .5 FL OZ

Relabeled by Preferred Pharmaceuticals, Inc.

EAR WAX REMOVAL DROPS carbamide peroxide - 6.5% solution/ drops Product Information Product Type HUMAN OTC DRUG Route of Administration HUMAN OTC DRUG TOPICAL

| Active Ingredient/Active Moiety | | | | |
|---|-----------------------|------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| CARBAMIDE PERO XIDE (UNII: 31PZ2VAU81) (HYDROGEN PERO XIDE - UNII:BBX060AN9V) | CARBAMIDE PEROXIDE | 65 mg in 1 mL | | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | |
| TARTARIC ACID (UNII: W48881119H) | | | |

| Packaging | | | |
|------------------------|---|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:68788- 7498-1 | 1 in 1 CARTON | 03/02/2020 | |
| 1 | 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 | 03/02/2020 | | |
| | | | | |

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

| Establishment | | | | | |
|---------------------------------|---------|-----------|---------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Preferred Pharmaceuticals, Inc. | | 791119022 | RELABEL(68788-7498) | | |

Revised: 3/2020 Preferred Pharmaceuticals, Inc.