

EAR WAX REMOVAL DROPS- carbamide peroxide - 6.5% solution/ drops GOODSENSE

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.

Goodsense Ear wax Remover

Active ingredient

Carbamide Peroxide, 6.5%

□ Purpose

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

- 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.

☐ **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.

☐ **Inactive ingredients**

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

Principal Display Panel Bottle Label 0.5 FL OZ

Goodsense NDC 50804-341-51

Ear Wax Removal drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15ml)

GOODSENSE®

Non-Irritating

Ear Wax Removal Drops

6.5% Carbamide Peroxide

0.5 FL OZ (15 mL)

DO NOT USE IF TAMPER EVIDENT SHRINK FILM ON BOTTLE IS BROKEN OR MISSING

Drug Facts

Active ingredient

Carbamide peroxide 6.5%.....Ear wax removal aid

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

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 ear wax remains after use of this product

Keep this and all drugs 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 • 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 the ear with warm water using a soft rubber bulb ear syringe
Children under 12 years: consult a doctor

See carton for full labeling

Distributed by:
Perrigo Direct, Inc.
Peachtree City, GA 30269
www.PerrigoDirect.com
1-800-222-1087

GoodSense® is a registered trademark of L. Perrigo Company 790866

Principal Display Panel - Carton label 0.5 FL OZ

Goodsense NDC 50804-341-51

Ear wax Remover Drops

Carbamide Peroxide 6.5%

Ear wax removal aid

0.5 FL OZ (15ml)

GOODSENSE®

Ear Wax Removal Drops

6.5% Carbamide Peroxide

DO NOT USE IF SAFETY SEAL IS TORN OR MISSING

Drug Facts

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

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 ear wax remains after use of this product

Keep this and all drugs 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 • 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 the ear with warm water, using a soft rubber bulb ear syringe
children under 12 years: consult a doctor

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Drug Facts (continued)

Other information

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

Inactive

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

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

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

GoodSense® is a registered trademark of L. Perrigo Company

NDC 50804-341-61

GOODSENSE®

Non-Irritating

Ear Wax Removal Drops

6.5% Carbamide Peroxide

- Safe, Gentle, Non-irritating
- Easily Cleanses Ear With Foaming Action

Compare to active ingredients of Debrox®

0.5 FL OZ (15 mL)



ACTUAL SIZE



5426104

Principal Display Panel - Carton label KIT 0.5 FL OZ

Goodsense NDC 50804-341-61

Ear wax Remover Kit

Carbamide Peroxide 6.5%

Ear wax removal aid

0.5 FL OZ (15ml)



EAR WAX REMOVAL DROPS

carbamide peroxide - 6.5% solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-341
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	65 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:50804-341-51	1 in 1 CARTON	06/05/2019	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:50804-341-61	1 in 1 KIT	06/05/2019	
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 final	part344	06/05/2019	

Labeler - GOODSENSE (076059836)

Revised: 8/2021

GOODSENSE