

**EAR WAX REMOVAL DROPS EQUATE- carbamide peroxide - 6.5% solution/ drops
WALMART STORES 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%

□ 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

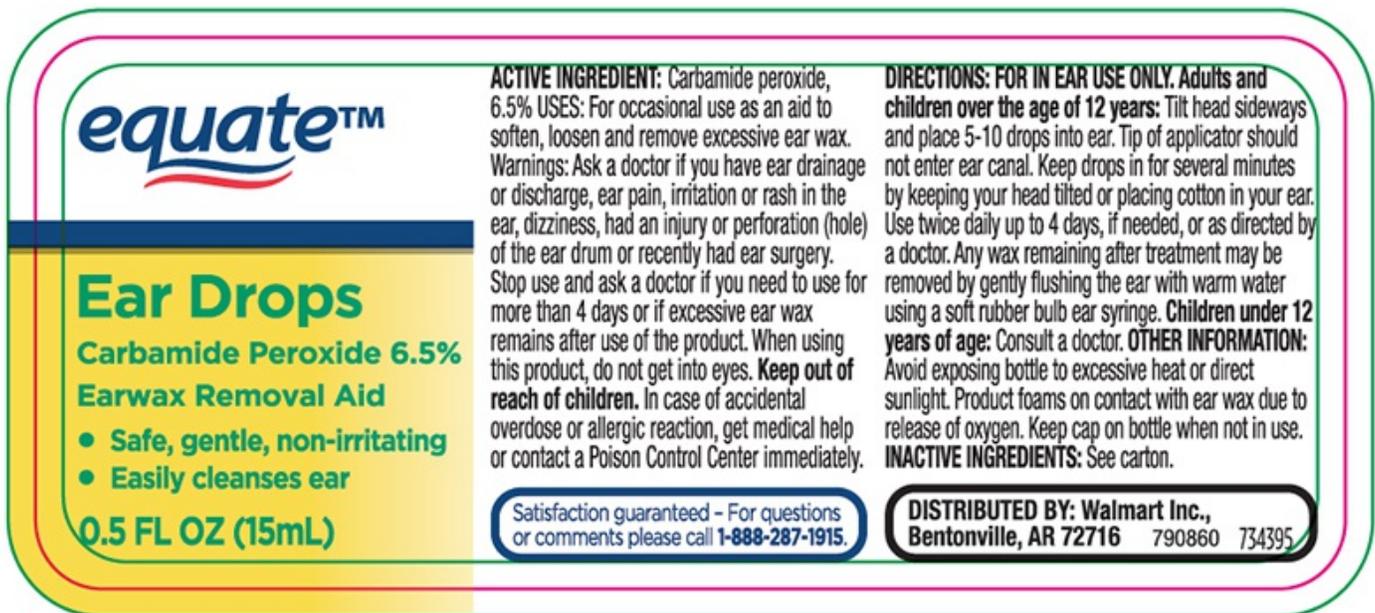
Principal Display Panel Bottle Label 0.5 FL OZ

Equate NDC 49035-862-02

Ear Wax Removal drops

Carbamide Peroxide 6.5%

0.5 FL OZ (15ml)



Principal Display Panel - Carton label 0.5 FL OZ

Equate NDC 49035-862-02

Ear wax Remover Drops

Carbamide Peroxide 6.5%

Ear wax removal aid

0.5 FL OZ (15ml)

equate™

Ear Drops
Carbamide Peroxide 6.5%
Earwax Removal Aid

5434068

equate™

NS 405-82-02

Compare to OTC Earwax Removal Aid

Ear Drops

Carbamide Peroxide 6.5%
Earwax Removal Aid

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

0.5 FL OZ (15mL)



Actual Size

Drug Facts (continued)

Other information

- 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 cracking.
- Keep cap on bottle when not in use.
- List no. and exp. date see label or bottom of box.

Inactive ingredients

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

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or concerns, please call 1-888-267-9933



DRUG FACTS FOR THE EAR DROPS

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 5-10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in for several minutes by keeping head tilted or placing cotton in 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: Consult a doctor

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Principal Display Panel - Carton label KIT 0.5 FL OZ

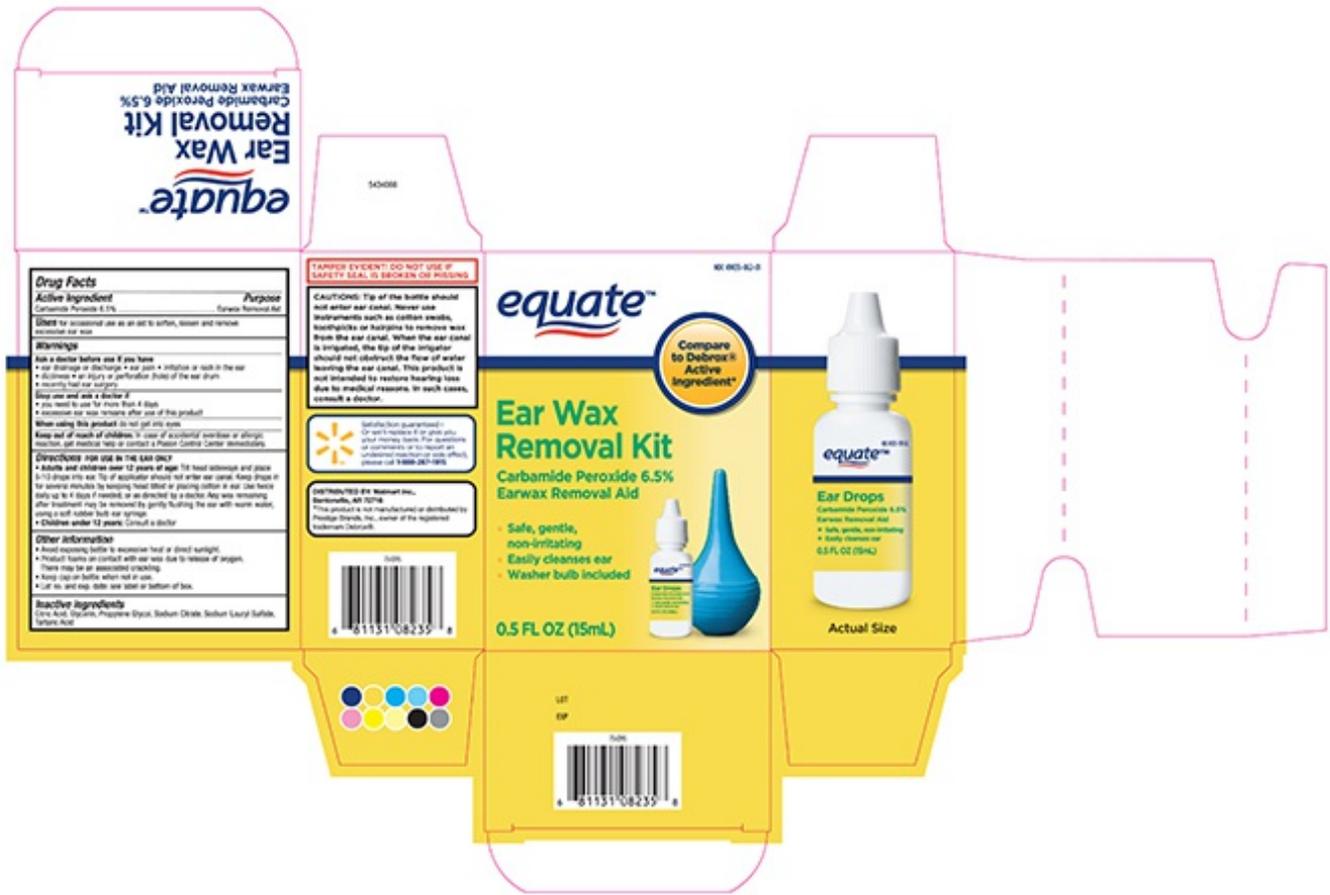
Equate NDC 49035-862-02

Ear wax Remover Kit

Carbamide Peroxide 6.5%

Ear wax removal aid

0.5 FL OZ (15ml)



EAR WAX REMOVAL DROPS EQUATE

carbamide peroxide - 6.5% solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-862
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: W4888119H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-862-02	1 in 1 CARTON	03/01/2019	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:49035-862-01	1 in 1 KIT	03/01/2019	
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	03/01/2019	

Labeler - WALMART STORES INC (051957769)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(49035-862)

Revised: 11/2018

WALMART STORES INC