

EAR WAX REMOVAL SYSTEM- carbamide peroxide - 6.50%

Walmart

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 Kit 13-243PQ

Step 1 Ear Wax Removal Drops

Active ingredient

Carbamide Peroxide - 6.50%

Purpose

Earwax removal aid

▯**Uses**▯ for occasional use as an aid to soften, loosen and remove excessive ear wax

Warnings

For external use only

Keep out of reach of the children

If product is 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 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

- Protect from heat and direct sunlight
- Keep cap on bottle when not in use

Inactive ingredient

Aloe Barbadosensis Leaf Extract
Chamomilla Recutita (Matricaria) Flower Extract
Glycerin
Mineral Oil
Oxyquinoline Sulfate
Water

Questions or comments?

1-866-483-2846

equate[®]

equate[®]

Compare
to Debrox[®]
Ingredient*

Ear Wax Removal Aid

Carbamide Peroxide 6.5%

- **Safe, gentle,
non-irritating**
- **Easily cleanses
ear with
foaming action**

Kit Includes
Soft Rubber Bulb
Ear Syringe and Drops

0.5 FL OZ (15 mL)



FOLD



Satisfaction guaranteed -
Or we'll replace it or give you
your money back. For questions
or comments or to report an
undesired reaction or side effect,
please call **1-888-287-1915**.

Distributed by: Wal-Mart Stores, Inc.,
Bentonville, AR 72716
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*This product is not manufactured or distributed by
GlaxoSmithKline, the distributor of Debrox[®].

EQT-EARKT-25



When used as directed, Equate® Ear Wax Removal Aid cleanses the ear with foaming action providing a safe, non-irritating method of softening and removing ear wax.

TAMPER EVIDENT Do not use if cap's printed band is missing or damaged
"SEALED FOR YOUR PROTECTION"

Drug Facts

Active ingredient	Purpose
Carbamide peroxide 6.5%	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

Drug Facts (continued)

Other information

- do not store above 86°F (30°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, flavor, glycerin, propylene glycol, sodium lauryl sarcosinate, sodium stannate, water

Questions? 1-888-287-1915

NOTE: Equate® Ear Wax Removal Aid will foam on contact with ear wax due to the release of oxygen.



EAR WAX REMOVAL SYSTEM

carbamide peroxide - 6.50% kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-554
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-554-07	1 in 1 KIT	08/15/20 14	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	15 mL

Part 1 of 1

EAR WAX REMOVAL DROPS WELL AT WALGREENS

carbamide peroxide - 6.50% solution/ drops

Product Information

Item Code (Source)	NDC:49035-552
Route of Administration	TOPICAL

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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
GLYCERIN (UNII: PDC6A3C0OX)	
OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-552-01	15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	08/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	10/04/2011	

Labeler - Walmart (051957769)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(49035-552) , pack(49035-554)

Revised: 1/2018

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