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	Purpose	
Carbamide Peroxide - 6.50%	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 cup on bottle when not in use

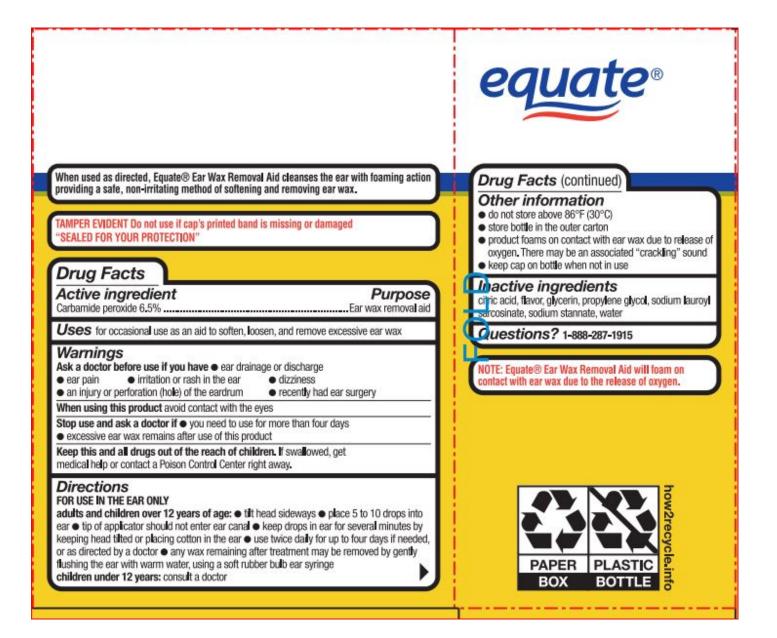
Inactive ingredient

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

Questions or comments?

1-866-483-2846





EAR WAX REMOVAL SYSTEM

carbamide peroxide - 6.50% kit

Product Inform	ation					
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-554			
Packaging						
# Item Code	e Package Description	on Marketing Start Date	Marketing End Date			
1 NDC:49035-554-07	7 1 in 1 KIT	08/15/2014				
Quantity of Parts						
Part #	Package Quantity	Total Product Quantity				
Part 1 1BOTTLE		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 PERO XIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE -CARBAMIDE 6.5 g UNII:BBX060AN9V) PEROXIDE in 100 mL **Inactive Ingredients Ingredient Name** Strength ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) CHAMO MILE (UNII: FGL3685T2X) GLYCERIN (UNII: PDC6A3C0OX) **OXYQUINOLINE SULFATE** (UNII: 61VUG75Y3P) MINERAL OIL (UNII: T5L8T28FGP) WATER (UNII: 059QF0KO0R) Packaging **Marketing Start** # Item Code **Package Description Marketing End Date** 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 10/04/2011 OTC monograph final part344

Labeler - Walmart (051957769)

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

Revised: 1/2018

Walmart