MURINE EAR WAX REMOVAL DROPS- carbamide peroxide liquid Prestige Brands Holdings, 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.

Murine Ear Wax Removal Drops

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

For external use only

Do not use

this product for more than 4 days

Ask a doctor before use

- if you have ear drainage or discharge, ear pain, irritation, a rash in the ear or are dizzy
- if you have an injury or perforation (hole) of the eardrum or after ear surgery

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

excessive ear wax remains after 4-day treatment with this product

Never insert cotton swabs, toothpicks, hairpins or other objects into the ear canal to remove earwax.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.

Directions

FOR USE IN THE EAR ONLY. Remove any hearing aids before using this product.

• **Adults and children over 12 years of age:** tilt head sideways and place 5 to 10 drops into ear canal.

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. The tip of the ear syringe should not obstruct the flow of fluid leaving the ear.

Children under 12 years of age: consult a doctor.

Other information

- Murine® Ear Drops foam upon being placed in the ear due to the release of oxygen.
- This product is not intended to restore hearing loss due to medical reasons. In such cases, consult a doctor.
- Protect from heat and sunlight. Secure cap tightly on bottle when not in use.
- **Tamper-Evident:** Do not use if neckband on bottle is broken or missing.
- Check expiration date before using.

Inactive ingredients

alcohol, citric acid, glycerin, polysorbate 20, sodium citrate, tartaric acid

Questions? 1-877-854-0853

Murine.com

PRINCIPAL DISPLAY PANEL

Murine Ear Wax Removal Drops Carbamide Peroxide / Ear Wax Removal Aid 0.5 FL OZ (15 mL)



PRINCIPAL DISPLAY PANEL

Murine Ear Wax Removal System Carbamide Peroxide / Ear Wax Removal Aid 0.5 FL OZ (15 mL) & SYRINGE



MURINE EAR WAX REMOVAL DROPS

carbamide peroxide liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-361	
Route of Administration	AURICULAR (OTIC)			

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	
ALCOHOL (UNII: 3K9958V90M)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
TARTARIC ACID (UNII: W4888I119H)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67172-361- 01	1 in 1 CARTON	06/01/2012		
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			
2	NDC:67172-361- 02	1 in 1 CARTON	06/01/2012		
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	06/01/2012		

Labeler - Prestige Brands Holdings, Inc. (159655021)

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