

## **EAR SYSTEM GNP- carbamide peroxide 6.50%**

**Amerisource Bergen**

*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.*

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### **EarWax Removal Drops**

#### **Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Carbamide Peroxide 6.5%	Softens & removes wax

#### **Uses**

For occasional use as an aid soften, loosen, and remove excessive ear wax

#### **Warnings**

##### **Do not use**

- If you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor.
- If you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor.

**When using this product** avoid contact with eyes

**Stop use and ask a doctor if** excessive earwax remains after use of this product for four consecutive days

#### **Keep out of reach of the children**

If product is swallowed, get medical help or contact a Poison Control Center right away  
In case of accidental ingestion, seek professional or contact a Poison Control Center immediately.

#### **Directions**

##### **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.

#### **Inactive ingredients**

Glycerin, Oxyquinoline



# Ear System

Carbamide Peroxide (6.5%)



# Ear System

Carbamide Peroxide (6.5%)

**Safe, Fast Acting  
Doctor Recommended  
Ingredients**

NDC 24385-0503-05



# Ear System

Carbamide Peroxide (6.5%)

## Wax Removal System

**Safe, Fast Acting  
Doctor Recommended  
Ingredients**

0.5 fl oz (15 mL)  
+ irrigator

Compare to Murine®  
EARCare Drops  
active ingredient\*



# Ear System

Carbamide Peroxide (6.5%)

**Safe, Fast Acting  
Doctor Recommended  
Ingredients**

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

<b>Drug Facts</b>	
<b>Active ingredient</b> Carbamide Peroxide 6.5%.....	<b>Purpose</b> Softens & removes wax
<b>Uses</b> For occasional use as an aid to soften, loosen, and remove excessive ear wax.	
<b>Warnings</b> <b>Do not use</b> <ul style="list-style-type: none"> <li>• if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor.</li> <li>• if you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor.</li> <li>• for more than four consecutive days.</li> </ul>	
<b>When using this product</b> <ul style="list-style-type: none"> <li>• avoid contact with the eyes.</li> </ul>	
<b>Stop use and ask a doctor if</b> • excessive ear wax remains after use of this product for four consecutive days.	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.</b>	
<b>Directions</b> 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 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 of age: consult a doctor.	
<b>Other information</b> • Protect from heat and direct sunlight. • Keep cap on bottle when not in use.	
<b>Inactive ingredients</b> Glycerin, Oxyquinoline.	



# Ear System

Carbamide Peroxide (6.5%)

**Safe, Fast Acting  
Doctor Recommended  
Ingredients**

## EAR SYSTEM GNP

carbamide peroxide 6.50% kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24385-501
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24385-501-07	1 in 1 KIT; Type 0: Not a Combination Product	10/15/2003	

### Quantity of Parts

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

### Part 1 of 1

## WAX REMOVAL SYSTEM

carbamide peroxide 6.50% solution/ drops

**Product Information**

<b>Item Code (Source)</b>	NDC:24385-500
<b>Route of Administration</b>	TOPICAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Carbamide Peroxide</b> (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	Carbamide Peroxide	6.5 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>OXYQUINOLINE SULFATE</b> (UNII: 61VUG75Y3P)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:24385-500-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part344		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part344	10/15/2003	

**Labeler** - Amerisource Bergen (007914906)**Registrant** - Product Quest Mfg, LLC (927768135)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Product Quest Mfg, LLC		927768135	manufacture(24385-500, 24385-501) , label(24385-500, 24385-501)