GOOD NEIGHBOR PHARMACY EAR SYSTEM- carbamide peroxide solution/ drops AmerisourceBergen Drug Corporation

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.

Good Neighbor Pharmacy Ear System

Drug Facts

Active Ingredient

Active ingredient	Purpose
Carbamide Peroxide 6.5%	Softens & removes wax

Purpose

Softens & removes wax

Uses

For occasional use as an aid to 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.

• for more than four consecutive days.

When using this product

•avoid contact with the eyes.

Stop use and ask a doctor if

• excessive ear wax remains after use of this product for four consecutive days.

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.

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 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.

Other information

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

Inactive ingredients

Glycerin, Oxyquinoline.

Distributed By AmerisourceBergen 1300 Morris Drive Chesterbrook, PA 19087 Visit us at www.goodneighborpharmacy.com



GOOD NEIGHBOR PHARMACY EAR SYSTEM carbamide peroxide solution/ drops **Product Information Product** Type HUMAN OTC DRUG Item Code (Source) NDC:24385-503 **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength CARBAMIDE PERO XIDE (UNII: 31PZ2VAU81) (HYDROGEN PERO XIDE -CARBAMIDE 6.5 g UNII:BBX060AN9V) PEROXIDE in 100 mL **Inactive Ingredients** Strength **Ingredient Name** OXYQUINOLINE (UNII: 5UTX5635HP)

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:24385-503- 05	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product					
Marketing Information						
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part344	04/15/2003				

Labeler - AmerisourceBergen Drug Corporation (007914906)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(24385-503), label(24385-503)

Revised: 7/2015

AmerisourceBergen Drug Corporation