EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid
Humco Holding Group, 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.

Private Label Earwax Removal- 0096

Adults & Children over 12 yrs of age:

tilt head to the side and place 10 drops into the ear canal.

Tip of applicator should not enter into the ear canal

Keep drops in ear for several minutes by keeping head tilted sideways 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 yrs of age:

Consult a physician.

For occasional use as an aid to soften, loosen and remove excessive earwax.

Earwax Removal Aid

Warnings

For external use only

Ask a doctor before use if you have:

ear drainage or discharge

ear pain, irritation, or rash in the ear

recently had surgery

dizziness

an injury or perforation (hole) of the eardrum

Carbamide Peroxide 6.5%

Aloe Barbadensis Leaf Extract

Chamomilla Recutita (Matricaria) Flower Extract

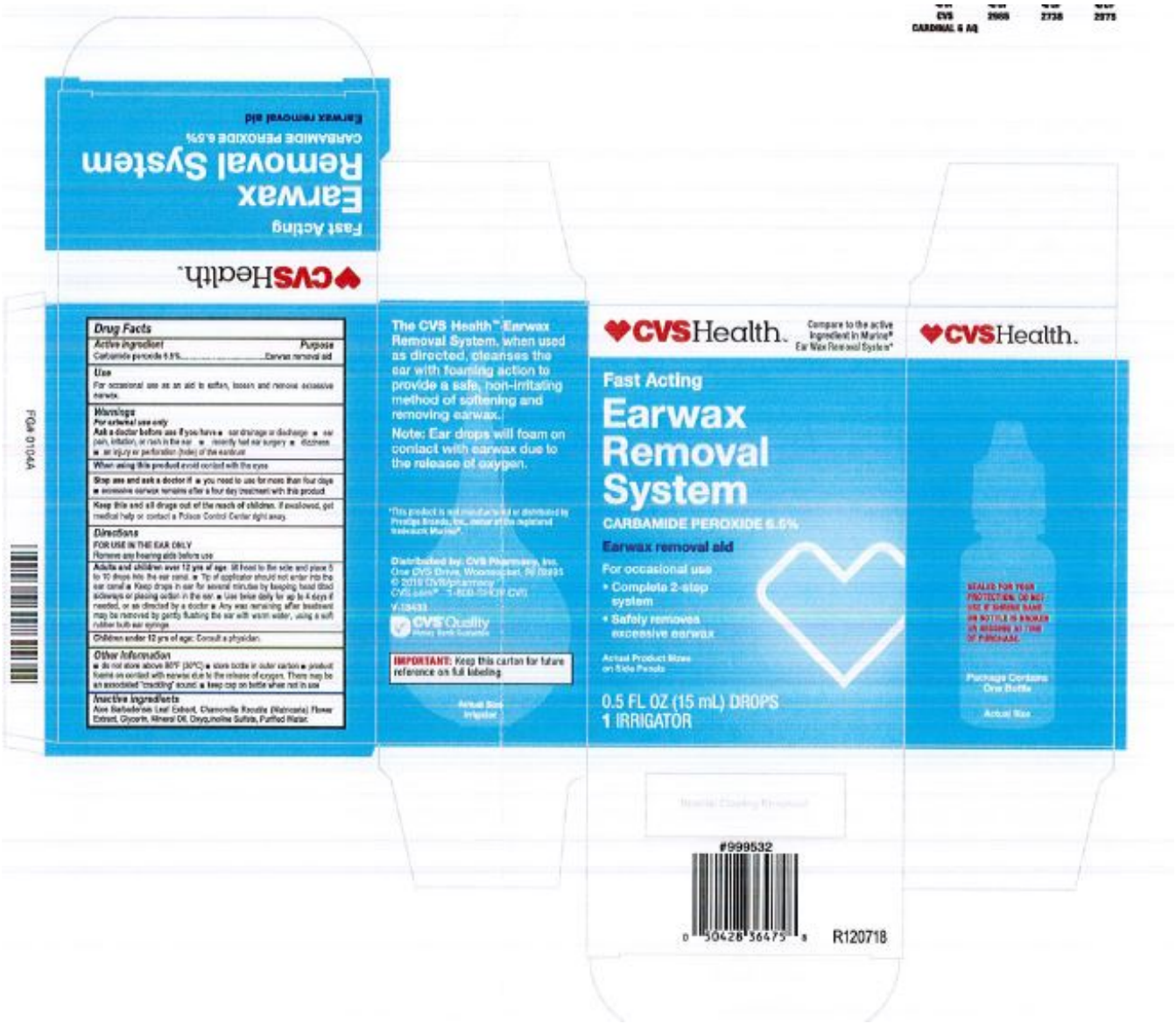
Glycerin

Mineral Oil

Oxyquinoline Sulfate

Purified Water

Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0395-9132
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	0.065 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHAMOMILE (UNII: FGL3685T2X)	
OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9132-45	1 in 1 CARTON	06/05/2019	
1		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	06/05/2019	

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-9132) , analysis(0395-9132) , label(0395-9132) , pack(0395-9132)

Revised: 3/2022 Humco Holding Group, Inc