

**TILCARE- carbamide peroxide solution/ drops**  
**Tilco Trading Pte. Ltd.**

*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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**Tilcare EARWAX REMOVAL AID EAR DROPS**

***Drug Facts***

***Active ingredient***

Carbamide peroxide 6.5%

***Purpose***

Earwax removal aid

***Use***

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

***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 ear drum or after ear surgery unless directed by a doctor.
- for more than four days.

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

**Stop use and ask a doctor if** excessive earwax remains after use of this product.

**Keep out of reach of children.** If 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***

- tamper evident: Do not use if outer carton is open, torn or missing.
- store bottle in the outer carton and keep the tip on bottle when not in use
- store at 20-25°C (68-77°F)
- drops foam in contact with earwax due to release of oxygen. You may experience a “crackling” sound

### **Inactive ingredients**

Glycerin, Lauroyl Sarcosine, Propylene Glycol

### **Questions?**

+1-844-324-5669

**You may also report serious side effects to this phone number.**

Gently Removes Excessive Earwax

Safe & Easy to Use

**Dist. by:** Tilco Trading PTE. LTD. 491B River Valley Road #15-01, Valley Point, Singapore - 248373

Made in USA

[www.tilcare.com/customers@tilcare.com](http://www.tilcare.com/customers@tilcare.com)

*Carbamide peroxide 6.5%*

### **Packaging**

**Tilcare**

**EARWAX  
REMOVAL AID  
EAR DROPS**

*Carbamide peroxide 6.5%*

**0.5 fl oz (15 mL)**

**DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING**

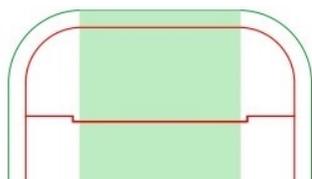
**ACTIVE INGREDIENT:** Carbamide peroxide, 6.5% **USE:** For occasional use as an aid to soften, loosen and remove excessive ear wax. **WARNINGS:** Do not use if you have ear drainage or discharge, ear pain, irritation or rash in the ear, are dizzy, have an injury or perforation (hole) of the eardrum or after ear surgery, consult a doctor. Stop use and ask a doctor if you need to use the drops for more than 4 days or if excessive ear wax remains after use of the product. When using this product, avoid contact with the eyes. **KEEP OUT OF REACH OF CHILDREN.** If 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 5-10 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:** Avoid exposing bottle to excessive heat or direct sunlight. Product foams on contact with ear wax due to release of oxygen. Keep cap on bottle when not in use.

**INACTIVE INGREDIENTS:** Glycerin, Lauroyl Sarcosine, Propylene Glycol

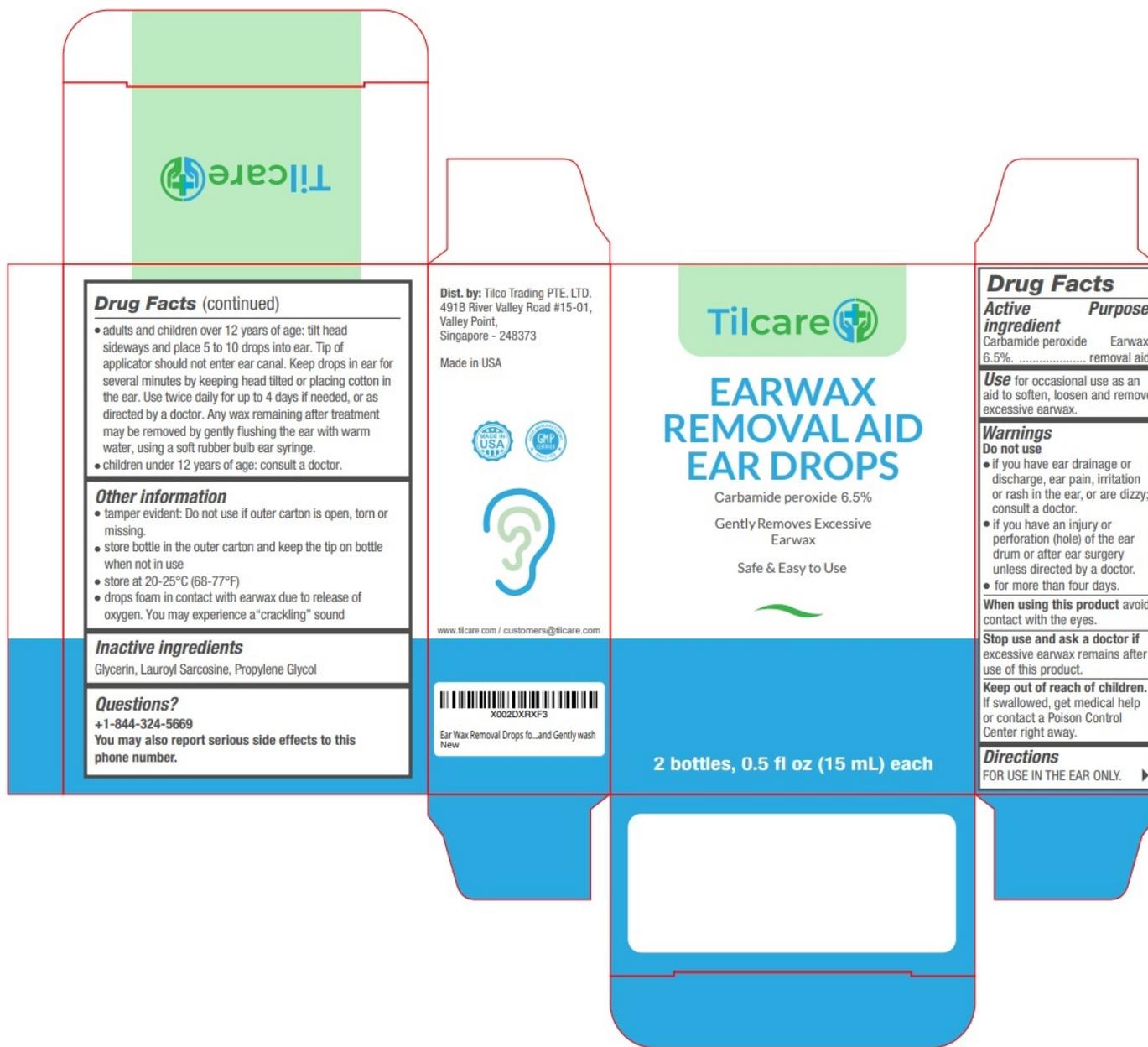
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## Packaging

## OUTER BOX LABEL OF TWO BOTTLES



### TILCARE

carbamide peroxide solution/ drops

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73390-101
<b>Route of Administration</b>	AURICULAR (OTIC)		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE -	CARBAMIDE	6.5 g

UNII:BBX060AN9V)		PEROXIDE	in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)				
LAUROYL SARCOSINE (UNII: LJ19P3L6F)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73390-101-15	1 in 1 BOX	10/23/2019	
1	NDC:73390-101-14	15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:73390-101-20	2 in 1 BOX	12/09/2019	
2	NDC:73390-101-14	15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<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	10/23/2019		

**Labeler** - Tilco Trading Pte. Ltd. (659506330)

Revised: 1/2021

Tilco Trading Pte. Ltd.