# SWIM-EAR- swim-ear solution Fougera Pharmaceuticals 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.

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Swim-EAR ® EAR DRYING AID

### **Drug Facts**

#### **Active ingredient**

Isopropyl alcohol, 95%

### **Purpose**

Ear drying aid

#### Uses

Dries water in the ears and relieves water-clogged ears after:

- swimming
- showering
- bathing
- washing the hair.

#### Warnings

**Flammable:** Keep away from fire or flame.

Do not use in the eyes.

#### Ask a doctor before use if you have

- ear drainage or discharge
- pain, irritation or rash in ear
- had ear surgery
- dizziness

**Stop use and ask a doctor if** irritation (too much burning) or pain occurs.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Apply 4 to 5 drops in each affected ear.

#### **Inactive ingredient**

Anhydrous glycerin 5% base.

#### E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc. Melville, New York 11747 IP4808C R10/12 #8

#### PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 1 Oz CONTAINER

NDC 0168-0126-91

Swim-EAR®

**EAR DRYING AID** 

29.57 mL (1 fl oz)



#### PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 1 Oz Carton

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#### **SWIM-EAR**

swim-ear solution

#### **Product Information**

HUMAN OTC DRUG Item Code (Source) NDC:0168-0126 Product Type

Route of Administration	AURICULAR (OTIC)
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Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL ALCOHOL	950 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0168-0126- 91	1 in 1 CARTON	04/03/1970		
1	29.57 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	04/03/1970		

# **Labeler -** Fougera Pharmaceuticals Inc. (043838424)

Revised: 11/2019 Fougera Pharmaceuticals Inc.