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.

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

NDC 0168-0126-91 Swim-EAR[®] EAR DRYING AID 29.57 mL (1 fl oz)

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NDC 0168-0126-01



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SWIM-EAR

swim-ear solution

Product Information

Swim-EAR[®] ...the ear drying aid that dries water ears after swimming, showering, bathing, and washing the hair. Used by swim leams for generations.

Pro	oduct Type		HUMAN OTC DRUG	Item Code	e (Soui	rce)	NDC:0	168-0126
Roi	ute of Admir	nistration	AURICULAR (OTIC)					
Act	tive Ingred	lient/Active	Moiety					
Ingredient Name					Basis of Strength		Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII: ND2M416302)					SOPROPYL ALCOHOL		950 mg in 1 mL	
Ina	active Ingr	edients						
Ingredient Name					Strength			
		mç						.9
GLY	(CERIN (UNII: P	•						.9
	CERIN (UNII: P	•						
Pa		PDC6A3C0OX)	ackage Description		Mark	eting Start Date		'keting End Date
Pa #	ckaging	PDC6A3C0OX)			Mark 04/03/1	Date		keting End
Pa # 1 ^N 0	ckaging Item Code NDC:0168- 0126-91	PDC6A3C0OX) Pi 1 in 1 CARTON	ackage Description	Not a		Date		keting End
Pa #	ckaging Item Code NDC:0168- 0126-91	PDC6A3C0OX) Pi 1 in 1 CARTON 29.57 mL in 1 B	ackage Description	Not a		Date		keting End
Pa # 1 1 0 1	ckaging Item Code NDC:0168- 0126-91	PDC6A3C0OX) Pi 1 in 1 CARTON 29.57 mL in 1 B	ackage Description OTTLE, DROPPER; Type 0: M oduct	Not a		Date		keting End
Pa # 1 1 0 1	ckaging Item Code NDC:0168- 0126-91	PDC6A3C0OX) Pa 1 in 1 CARTON 29.57 mL in 1 BG Combination Pro Informat	ackage Description OTTLE, DROPPER; Type 0: M oduct		04/03/1 Market	Date	Mar	keting End
Pa # 1 0 1	ckaging Item Code NDC:0168- 0126-91	PDC6A3C0OX) Particle Participation Participa	ackage Description OTTLE, DROPPER; Type 0: Moduct ion	graph I	04/03/1 Market	Date 970	Mar	keting End Date

Labeler - Fougera Pharmaceuticals Inc. (043838424)

Revised: 3/2021

Fougera Pharmaceuticals Inc.