

DEBROX SWIMMERS EAR- isopropyl alcohol liquid
Medtech Products 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.

Debrox Swimmers Ear

Drug Facts

Active ingredient

Purpose

Isopropyl alcohol 95% in an anhydrous glycerin 5% baseEar drying aid

Use

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
- ear pain, irritation or rash in the ear • dizziness
- recently had ear surgery

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 (1-800-222-1222) right away.

Directions

- unscrew cap from bottle
- remove foil safety seal from bottle
- affix applicator cap to bottle
- remove red applicator cap tip
- apply 4 to 5 drops in each affected ear

Other information

- recap bottle after each use
- keep away from heat or direct sunlight
- store at room temperature 15-25°C (59-77°F)
- do not use if foil seal imprinted with “SEALED FOR YOUR PROTECTION” under cap is broken or missing
- keep carton for full drug facts

Inactive

Glycerin

Questions?

1-800-344-7239 debrox.com

PRINCIPAL DISPLAY PANEL

Debrox® Swimmer's Ear

Isopropyl alcohol 95%

Ear Drying Drops

1 FL OZ (30 mL)



DEBROX SWIMMERS EAR

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-323
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	95 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	WHITE (CLEAR)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-323-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part344	04/01/2019	

Labeler - Medtech Products Inc. (122715688)

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Medtech Products Inc.