

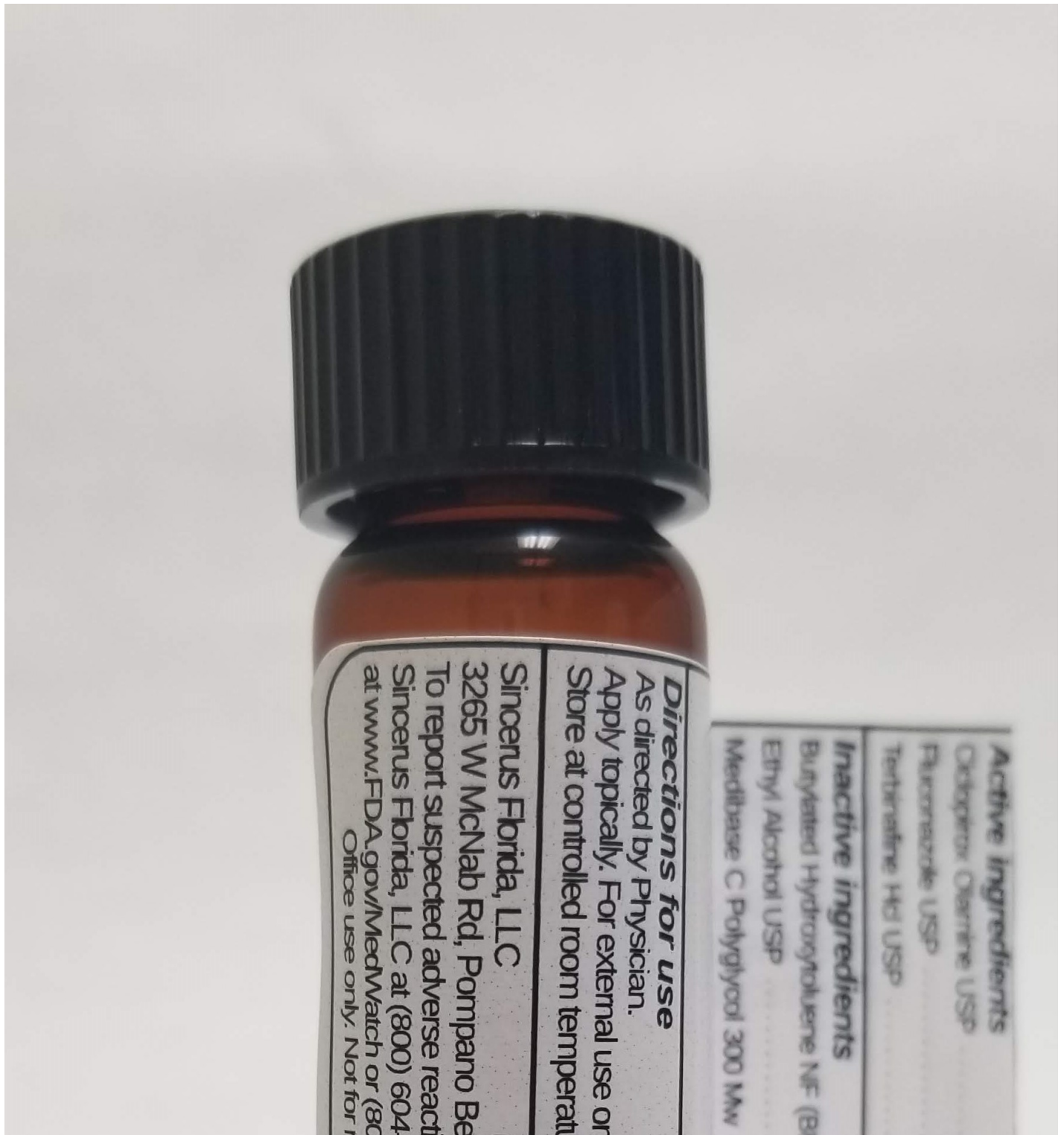
**CICLOPIROX 8% / FLUCONAZOLE 1% / TERBINAFINE HCL 1%- ciclopirox 8% / fluconazole 1% / terbinafine hcl 1% solution**

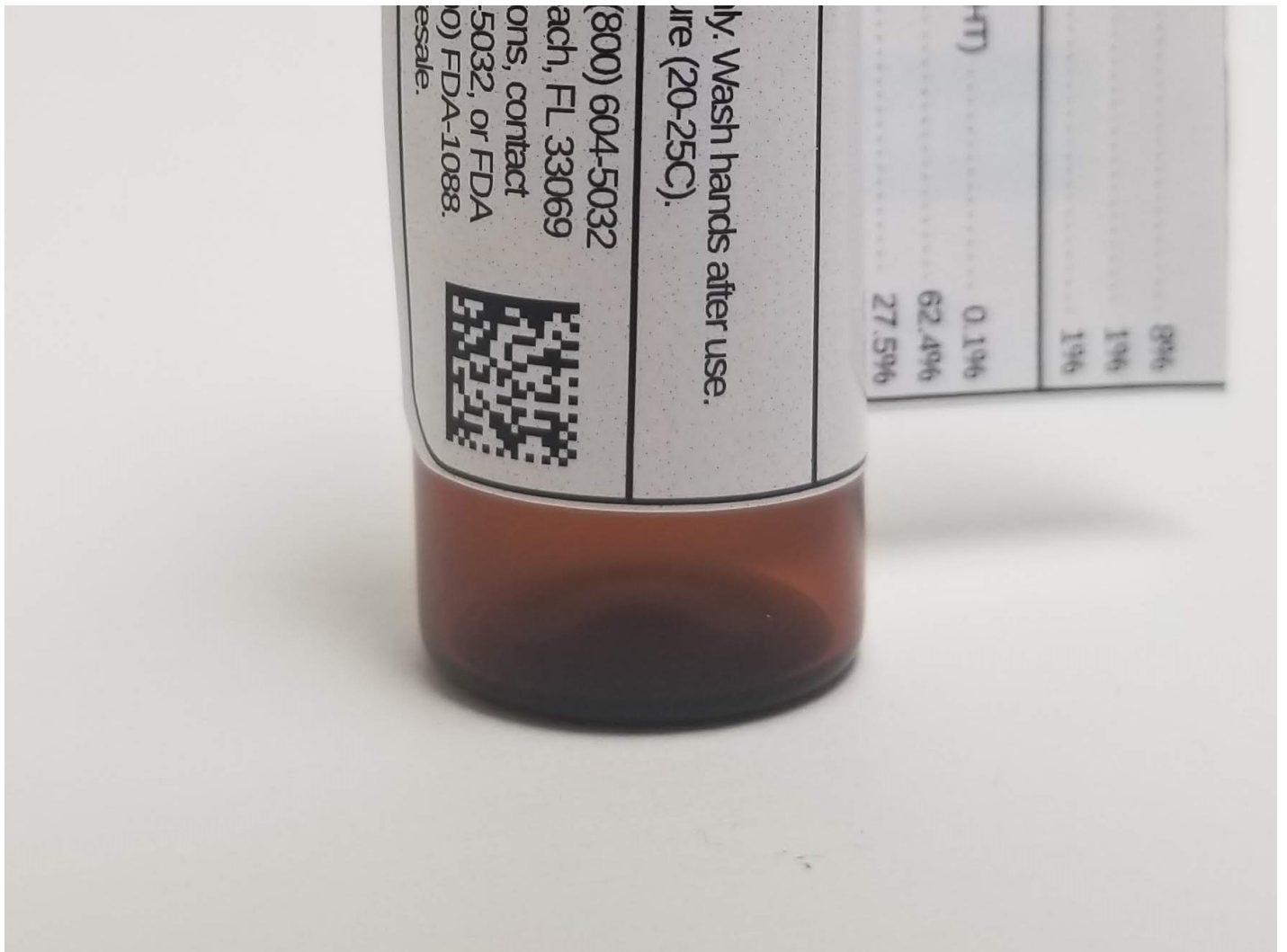
**Sincerus Florida, LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).*

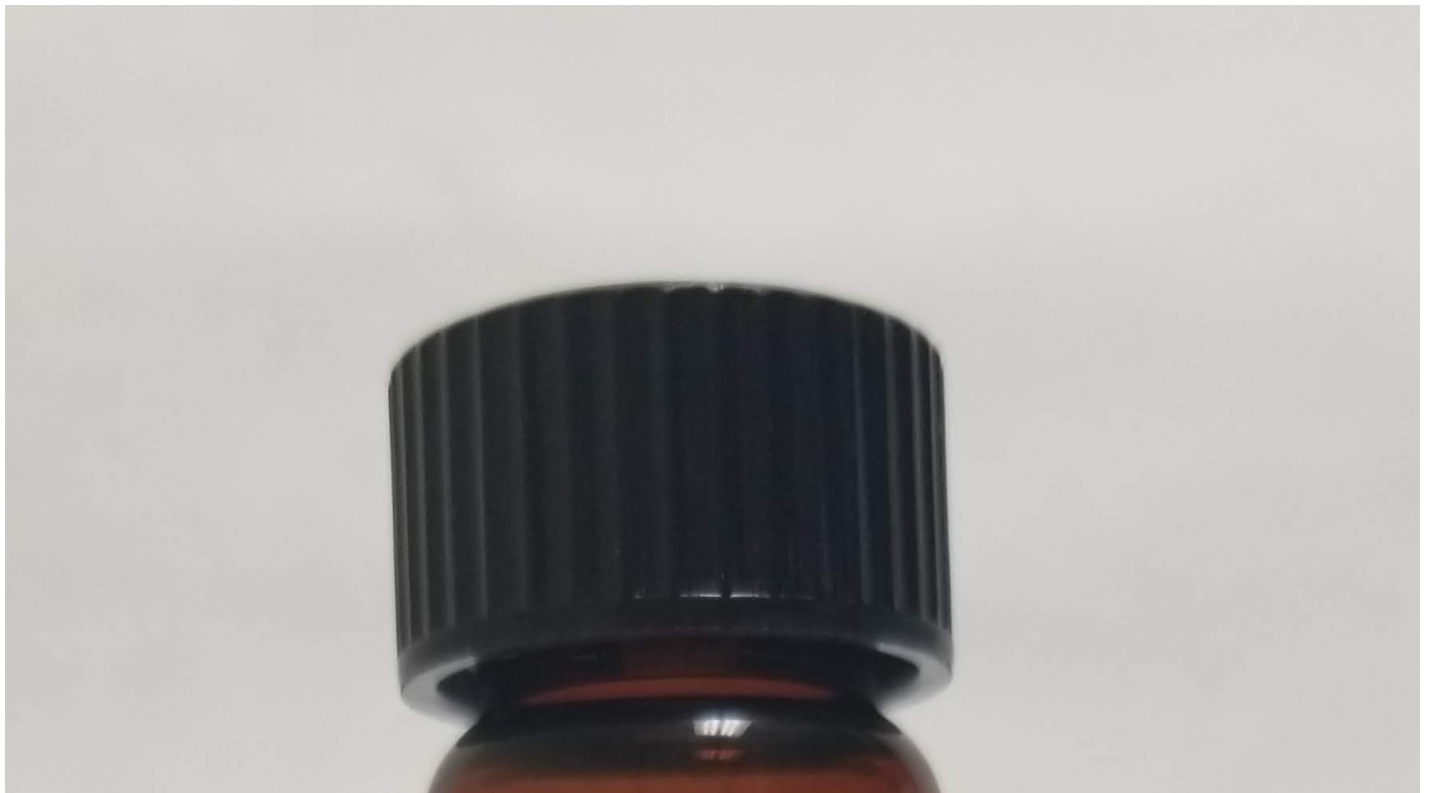
**CICLOPIROX 8% / FLUCONAZOLE 1% / TERBINAFINE HCL 1%**

**Directions for use**





**Sincerus Florida, LLC adverse reactions.**



<b>Active ingredients</b>	
Octogen Oxidant USP	896
Fluorazide USP	196
Tetrahydro HCl USP	196
<b>Inactive ingredients</b>	
Burylated Hydroxytoluene NF (BHT)	0.196
Ethyl Alcohol USP	62.496
Medibase C Polyglycol 300 Mw	27.596

**Directions for use**

As directed by Physician.  
 Apply topically. For external use only. Wash hands after use.  
 Store at controlled room temperature (20-25C).

Sincerus Florida, LLC (800) 604-5032  
 3265 W McNab Rd, Pompano Beach, FL 33069  
 To report suspected adverse reactions, contact  
 Sincerus Florida, LLC at (800) 604-5032, or FDA  
 at www.FDA.gov/MedWatch or (800) FDA-1088.  
 Office use only. Not for resale.



Active, inactive

**Active ingredients**

Ciclopirox Olamine USP  
Fluconazole USP  
Terbinafine Hcl USP

**Inactive ingredients**

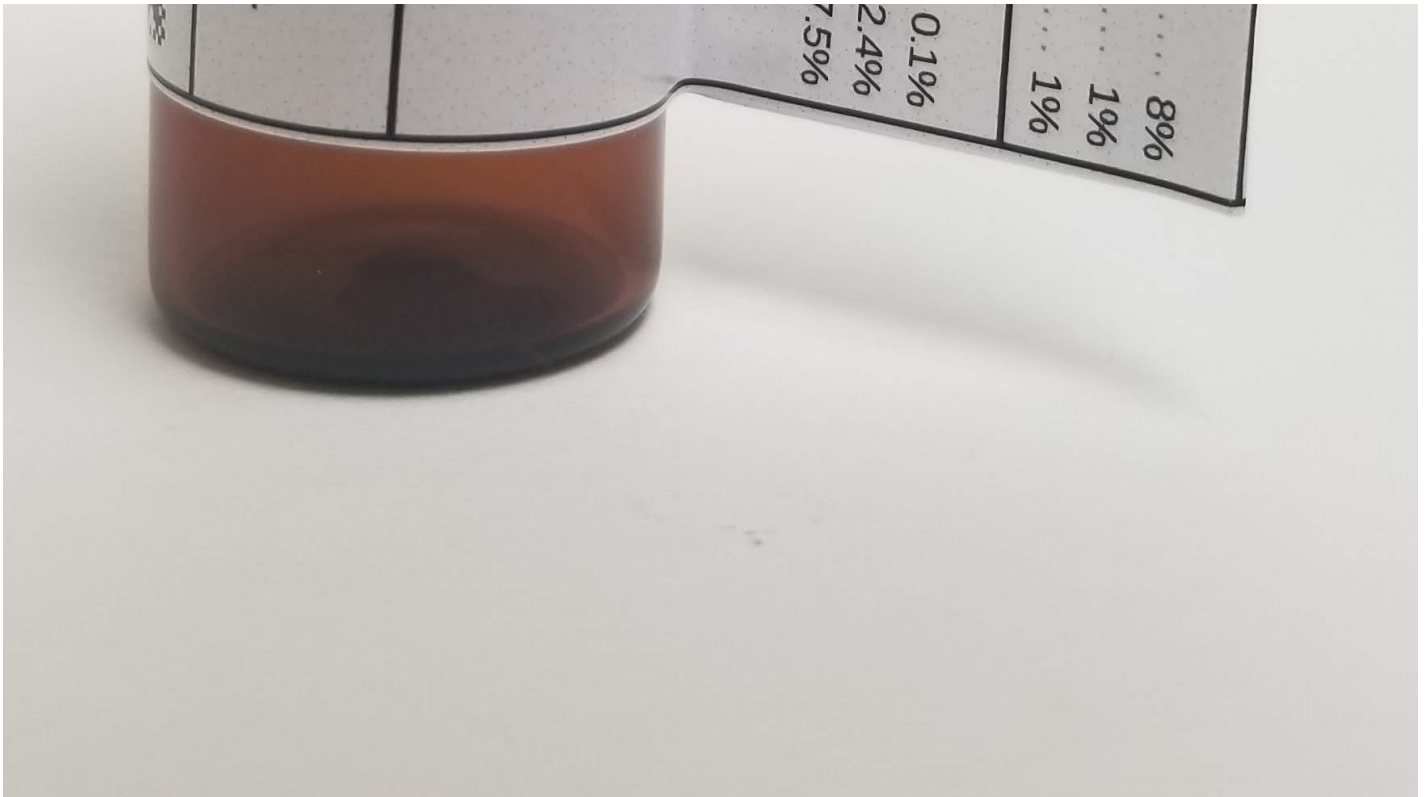
Butylated Hydroxytoluene NF (BHT)  
Ethyl Alcohol USP  
Medibase C Polyglycol 300 Mw

**Directions for use**

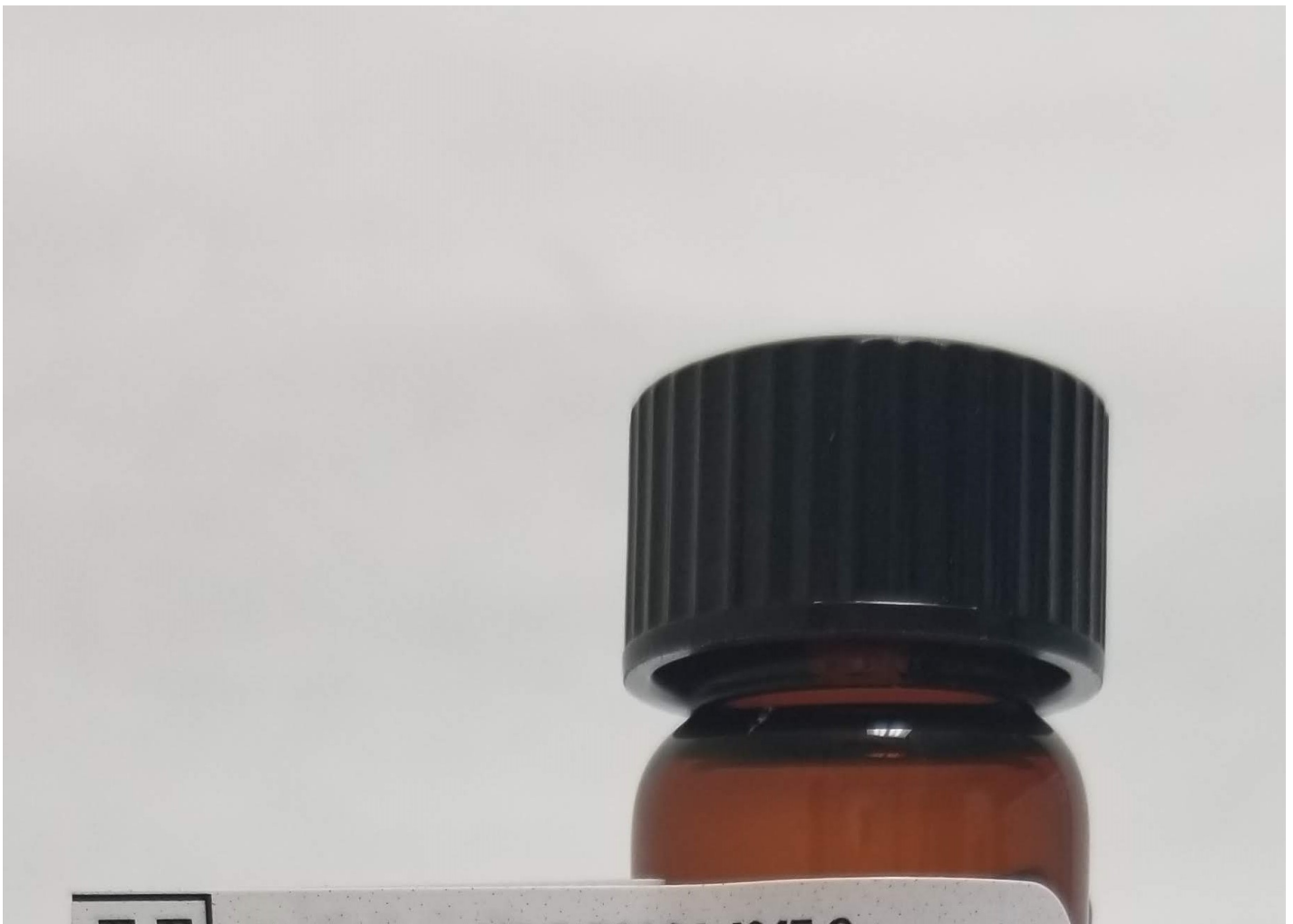
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Store at controlled room temperature (20-25C).

Sinoerus Florida, LLC  
3265 W McNab Rd, Pompano Beach, FL 33069  
(800) 604-5032

**4433**



**NDC 72934-4045-9 CICLOPIROX OLAMINE USP 8% / FLUCONAZOLE USP 1% /  
TERBINAFINE HCL USP 1%. Solution 15gm**



NDC 72934-4045-9

CICLOPIROX OLAMINE USP  
8%  
FLUCONAZOLE USP 1%  
TERBINAFINE HCL USP 1%  
SOLUTION 15gm

Rx only  
BUD: 01/01/1970

Lot: 071040ABCDEF@1  
MFG: 01/01/1970



This is a compounded drug.  
Made in USA

**CICLOPIROX 8% / FLUCONAZOLE 1% / TERBINAFINE HCL 1%**

ciclopirox 8% / fluconazole 1% / terbinafine hcl 1% solution

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72934-4045
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CICLOPIROX (UNII: 19W019ZDRJ) (CICLOPIROX - UNII:19W019ZDRJ)	CICLOPIROX	8 g in 100 g
FLUCONAZOLE (UNII: 8VZV102JFY) (FLUCONAZOLE - UNII:8VZV102JFY)	FLUCONAZOLE	1 g in 100 g
TERBINAFINE (UNII: G7RIW8S0XP) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE	1 g in 100 g

**Product Characteristics**

Color	white (CLEAR SOLUTION)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-4045-9	15 g in 1 VIAL, GLASS; Type 0: Not a Combination Product	05/01/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2019	

**Labeler** - Sincerus Florida, LLC (080105003)**Establishment**

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-4045)

Revised: 4/2019

Sincerus Florida, LLC