# AZELAIC ACID 15% / NIACINAMIDE 4% - azelaic acid 15% / niacinamide 4% cream Sincerus Florida, LLC

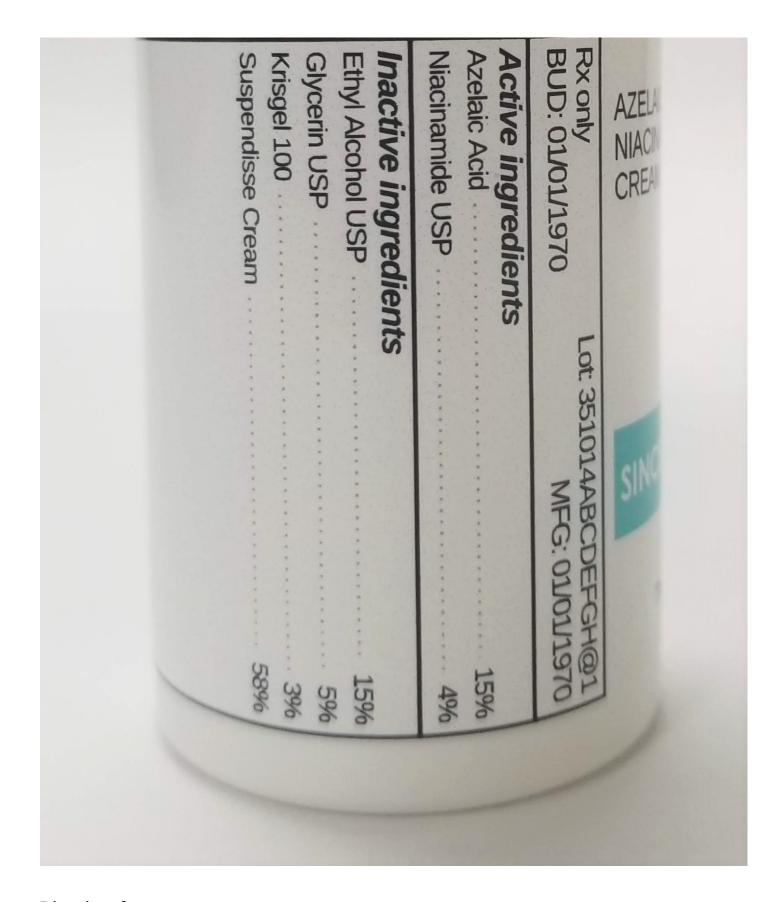
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

-----

### **AZELAIC ACID 15% / NIACINAMIDE 4%**

### Active, inactive



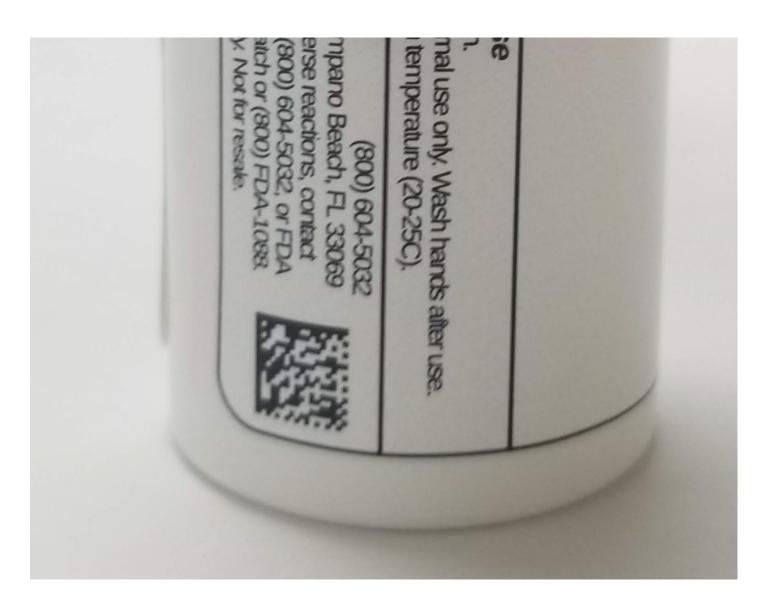


### Directions for use

Directions for us
As directed by Physician
Apply topically. For exter

Store at controlled room

Sincerus Florida, LLC 3265 W McNab Rd, Por To report suspected adv Sincerus Florida, LLC at at www.FDA.gov/MedWe Office use on



Sincerus Florida, LLC adverse reactions.



# Directions for use

As directed by Physician.

Store at controlled room temperature (20-25C). Apply topically. For external use only. Wash hands a

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



NDC 72934-2008-2 AZELAIC ACID 15%, NIACINAMIDE USP 4%, CREAM 30gm





Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-2008	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AZELAIC ACID (UNII: F2VW3D43YT) (AZELAIC ACID - UNII:F2VW3D43YT)	AZELAIC ACID	15 g in 100 g	
NIACINAMIDE (UNII: 25X5118 RD4) (NIACINAMIDE - UNII:25X5118 RD4)	NIACINAMIDE	4 g in 100 g	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1 NI 2	DC:72934-2008-	30 g in 1 BOTTLE, PUMP; 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(72934-2008)	

Revised: 4/2019 Sincerus Florida, LLC