

**011218 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN 0.025% - 011218  
niacinamide 2% / spironolactone 5% / tretinoin 0.025% gel  
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](#).*

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**011218 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN 0.025%**

**Directions for use**



**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](http://www.FDA.gov/MedWatch) or (800) FDA-1088.

Office use only. Not for resale. LS-01-000000-00



Sincerus Florida, LLC adverse reactions

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Sincerus Florida, LLC

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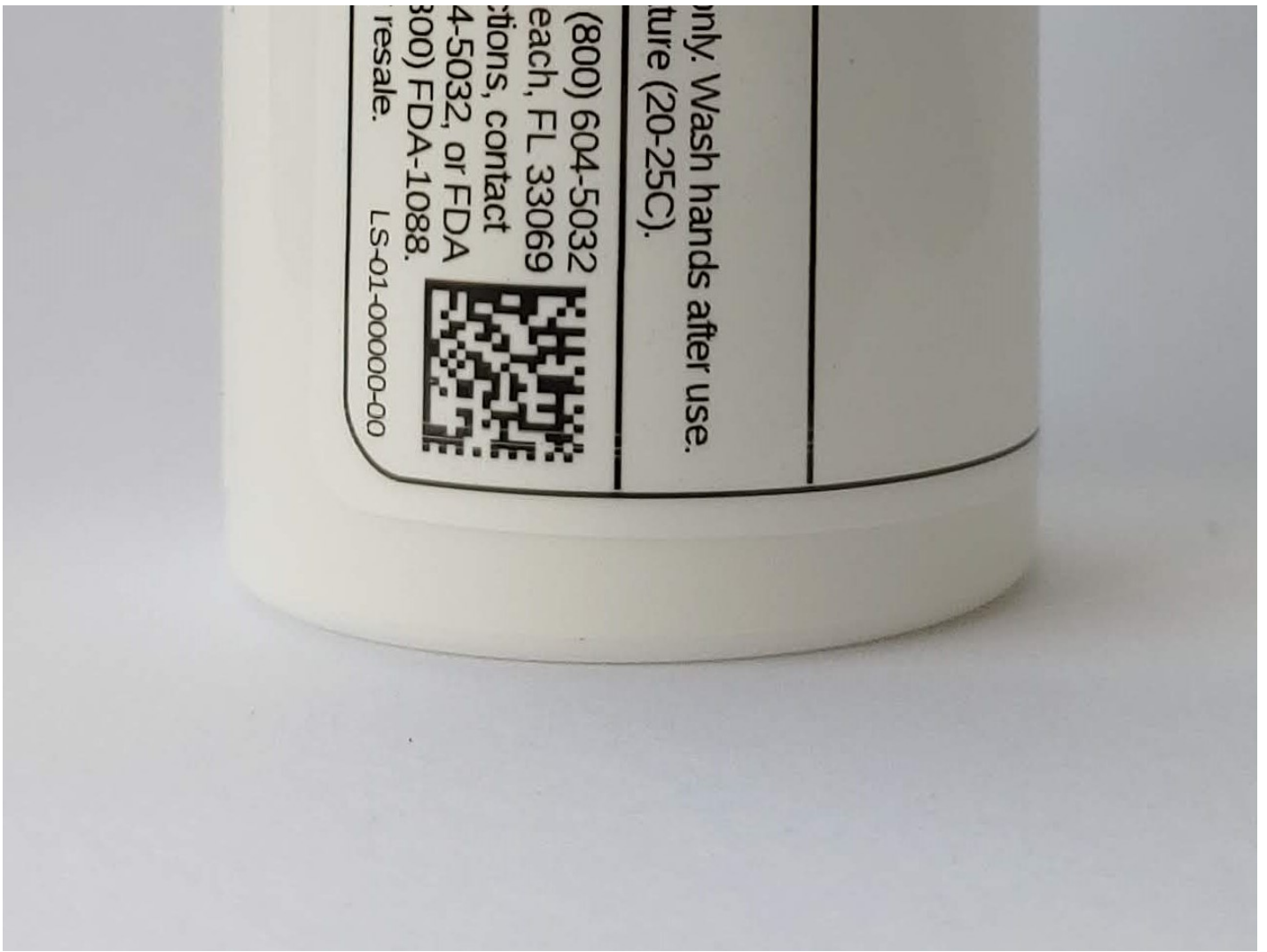
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Sincerus Florida, LLC at (800) 60

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Office use only. Not for





**Active, inactive**



011218  
NIACINAMIDE  
SPIRONOLACTONE  
TRETINOIN  
GEL

Rx only

BUD: XXXXXXXXXXXX

Lot: 011218XXXXXXXXXXXX@XX

MFG: XXXXXXXXXXXX

**Active ingredients**

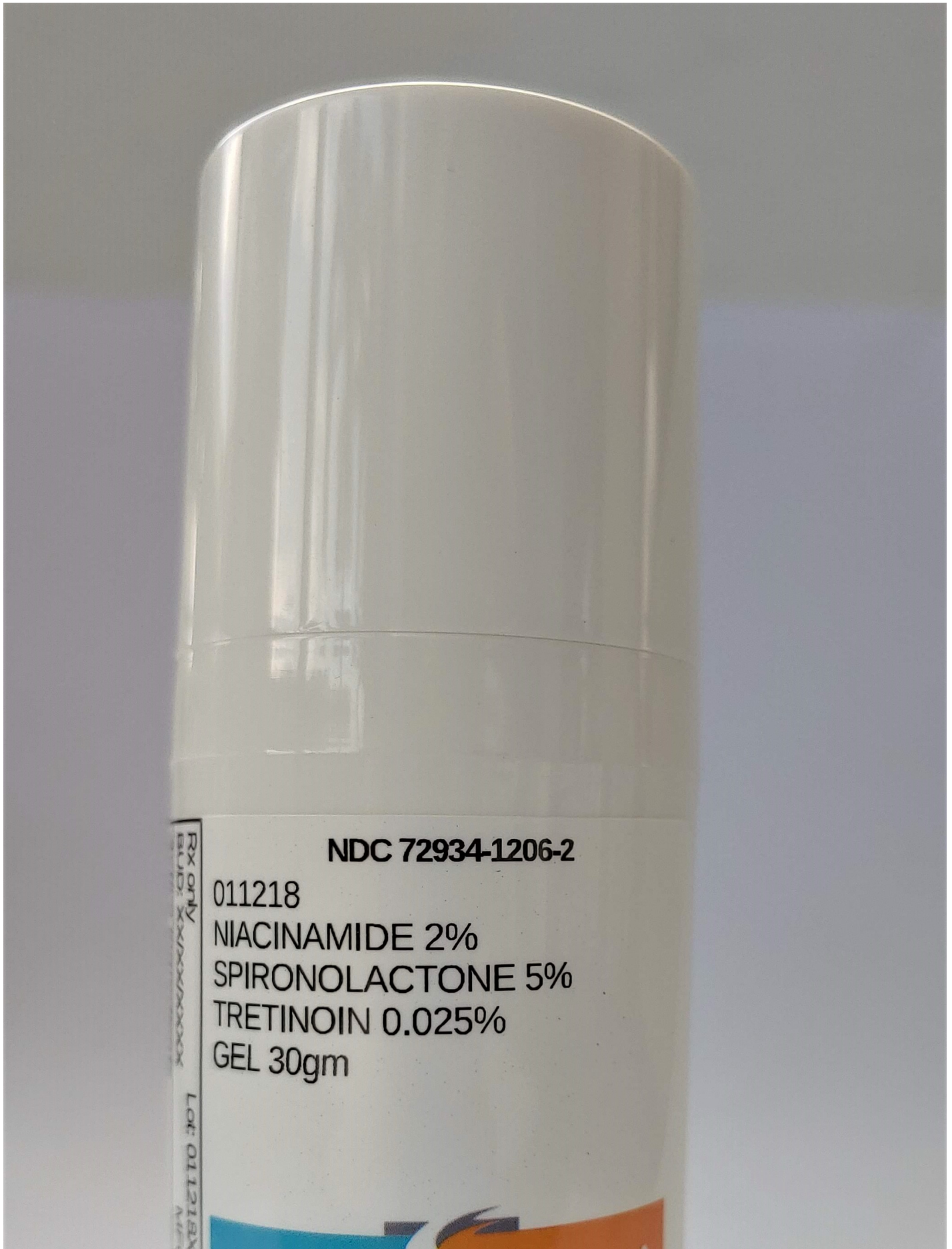
Niacinamide USP ..... 2%  
Spironolactone USP ..... 5%  
Tretinoin USP ..... 0.025%

**Inactive ingredients**

Ascorbyl Palmitate FCC ..... 1%  
Butylated Hydroxytoluene NF (BHT) ..... 0.2%  
Glycerin And Artificial Rose Water ..... 5%  
Sodium Metabisulfite NF ..... 0.2%  
Suspendisse Gel ..... 85.325%



**NDC 72934-1206-2 011218 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN  
0.025% gel 30 gm**



**NDC 72934-1206-2**

011218

NIACINAMIDE 2%

SPIRONOLACTONE 5%

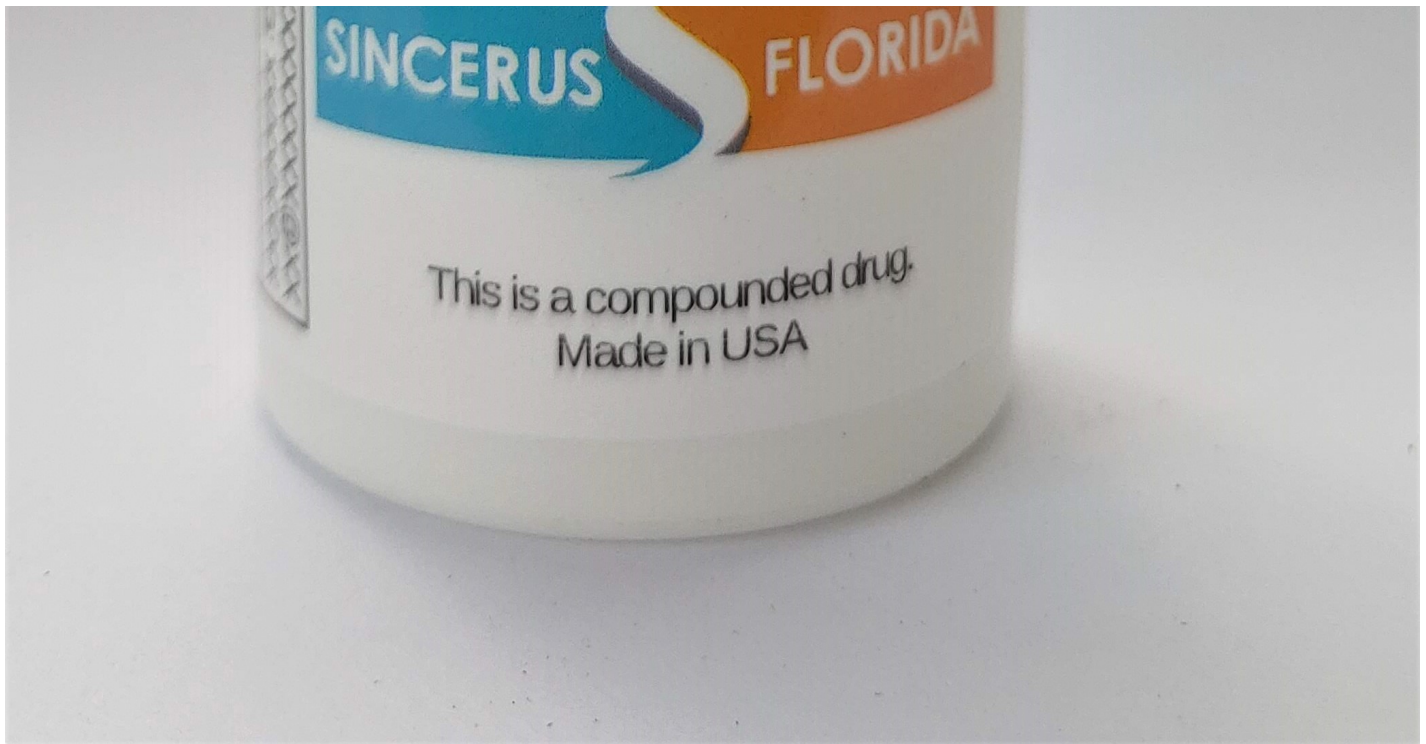
TRETINOIN 0.025%

GEL 30gm

Rx only

XXXXXXXXXX

Lot: 011218X



**011218 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN 0.025%**

011218 niacinamide 2% / spironolactone 5% / tretinoin 0.025% gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72934-1206
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	2 g in 100 g
SPIRONOLACTONE (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232)	SPIRONOLACTONE	5 g in 100 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.025 g in 100 g

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1206-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/02/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/02/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	api manufacture(72934-1206)

Revised: 7/2020

Sincerus Florida, LLC