

**011220 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN 0.05% - 011220
niacinamide 2% / spironolactone 5% / tretinoin 0.05% 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](#).

011220 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN 0.05%

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 or (800) FDA-1088.

Office use only. Not for resale.

LS-01-000000-00



Sincerus Florida, LLC adverse reactions

Directions for use

As directed by Physician.

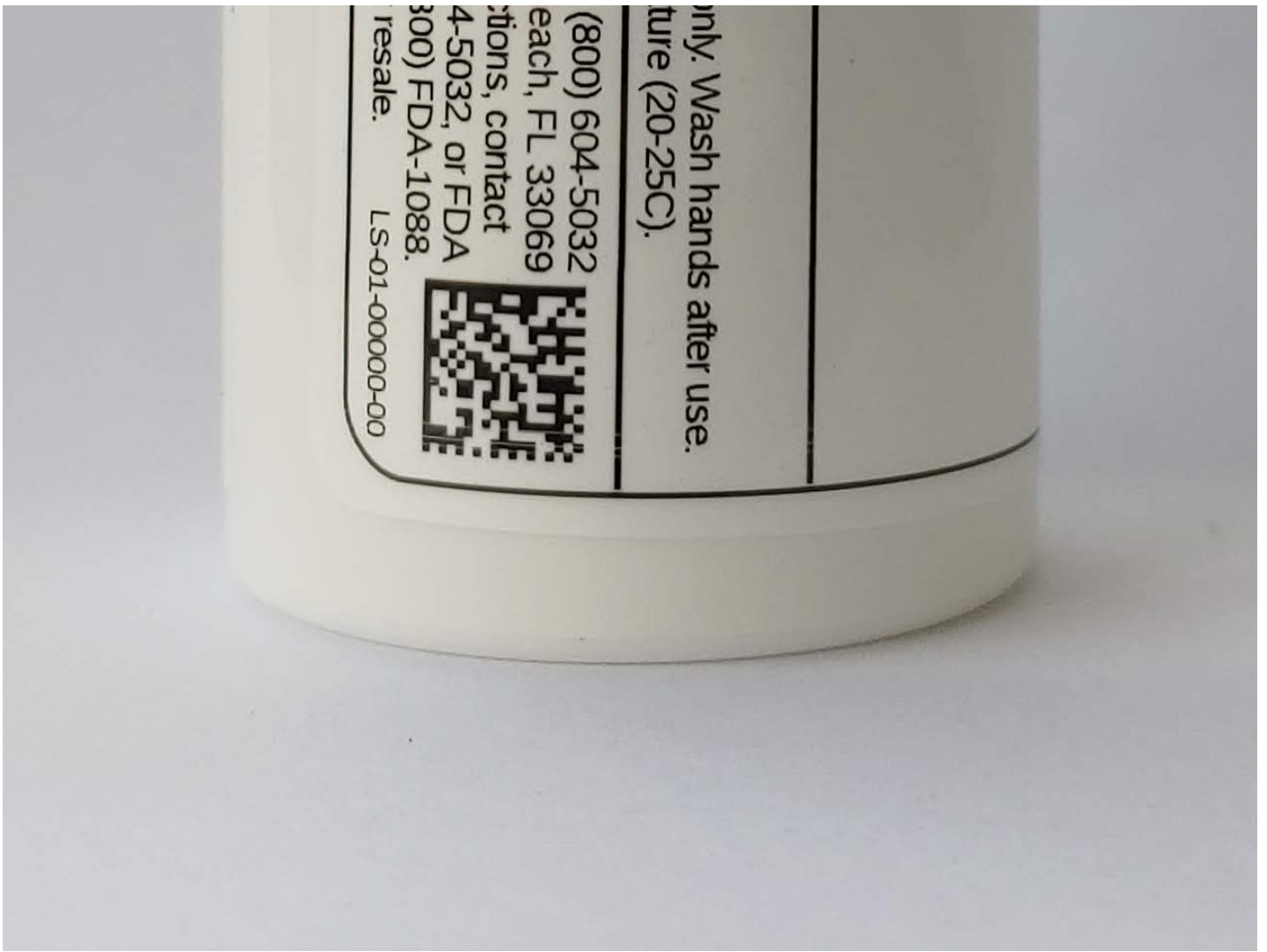
Apply topically. For external use only.
Store at controlled room temperature.

Sincerus Florida, LLC

3265 W McNab Rd, Pompano Beach, FL 33069

To report suspected adverse reactions, contact Sincerus Florida, LLC at (800) 600-3333 or at www.FDA.gov/MedWatch or (800) 332-1088.

Office use only. Not for patient use.



Active, inactive



U S P



Rx only Lot: 011220XXXXXXXXXX@XX
BUD: XXXXXXXXXXXX MFG: XXXXXXXXXXXX

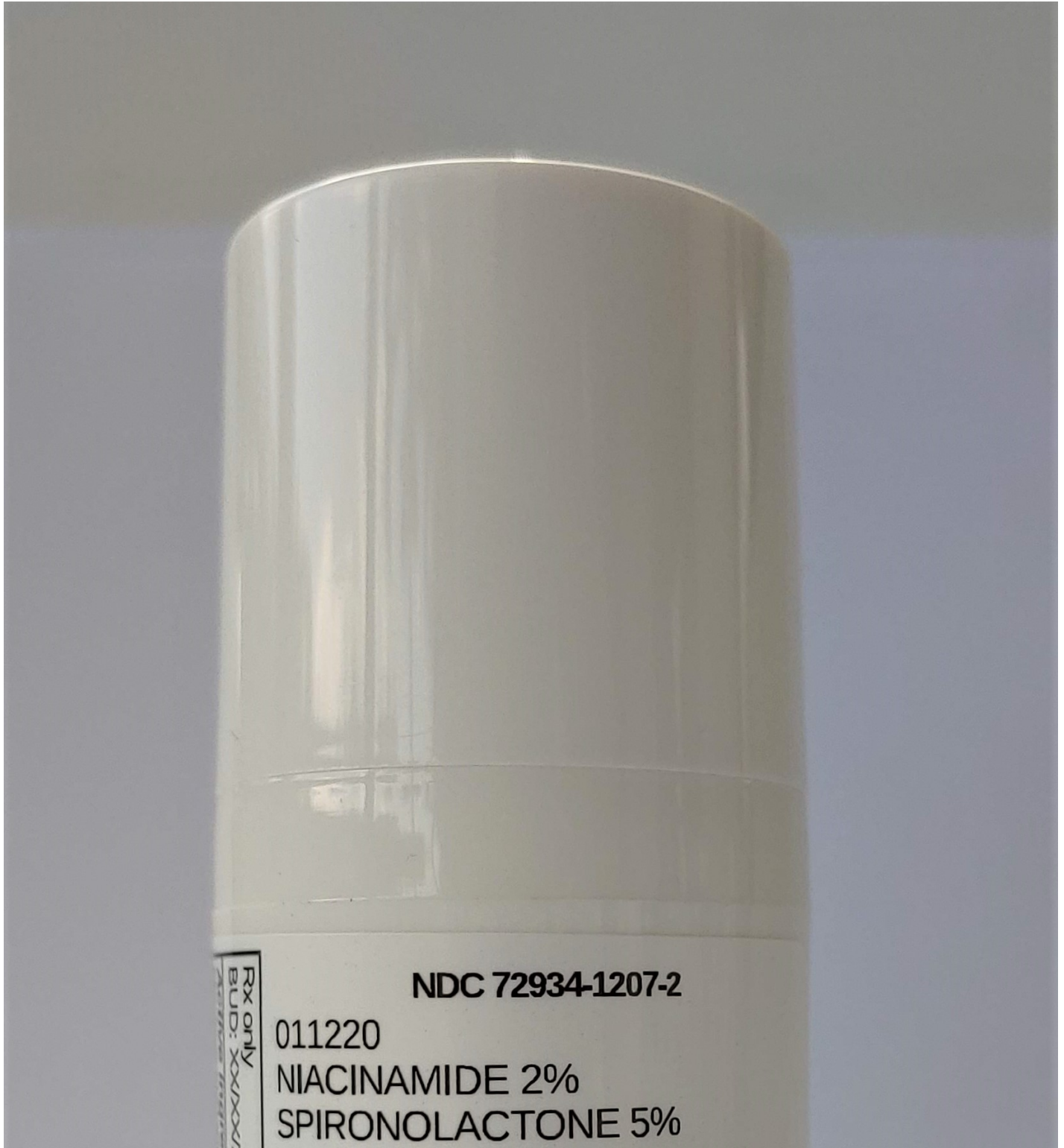
Active ingredients

Niacinamide USP 2%
Spironolactone USP 5%
Tretinoin USP 0.05%

Inactive ingredients

Ascorbyl Palmitate FCC 1%
Butylated Hydroxytoluene NF (BHT) 0.1%
Glycerin And Artificial Rose Water 5%
Sodium Metabisulfite NF 0.2%
Suspendisse Gel 85.4%

**NDC 72934-1207-2 011220 NIACINAMIDE 2% / SPIRONOLACTONE 5% / TRETINOIN
0.05% gel 30 gm**





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011220 niacinamide 2% / spironolactone 5% / tretinoin 0.05% gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-1207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SPIRONOLACTONE (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232)	SPIRONOLACTONE	5 g in 100 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.05 g in 100 g
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	2 g in 100 g

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1207-2	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	manufacture(72934-1207)

Revised: 7/2020

Sincerus Florida, LLC