

011503 DAPSONE 6% / NIACINAMIDE 2% / SPIRONOLACTONE 5% - 011503 dapsone 6% / niacinamide 2% / spironolactone 5% 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](#).

011503 DAPSONE 6% / NIACINAMIDE 2% / SPIRONOLACTONE 5%

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

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Sincerus Florida, LLC

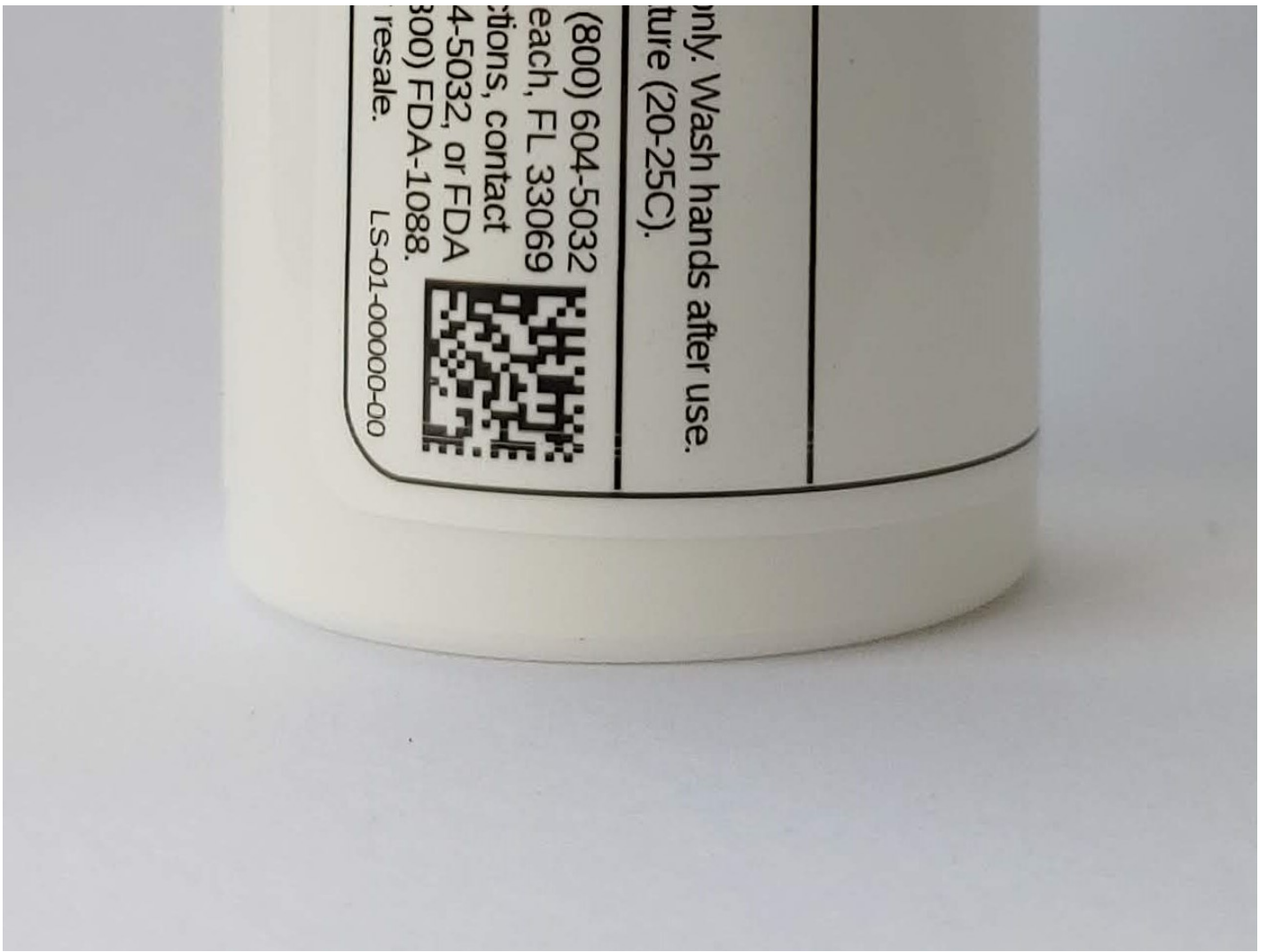
3265 W McNab Rd, Pompano B

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Sincerus Florida, LLC at (800) 60

at www.FDA.gov/MedWatch or (8

Office use only. Not for



Active, Inactive



011503
DAPSONE
NIACINAMIDE
SPIRONOLACTONE
GEL 30 gm

SING

Rx only
Lot: 011503XXXXXXXXXXXX@XXX
BUD: XXXXXXXXXXXX
MFG: XXXXXXXXXXXX

Active ingredients

Dapsone USP 6%
Niacinamide USP 2%
Spironolactone USP 5%

Inactive ingredients

Butylated Hydroxytoluene NF (BHT) 0.1%
Lavender Oil 0.25%
Propylene Glycol USP 5%
Suspendisse Gel 81.65%

NDC 72934-1211-2 011503 DAPSONE 6% / NIACINAMIDE 2% / SPIRONOLACTONE 5% gel 30 gm

NDC 72934-1211-2

011503

DAPSONE 6%

NIACINAMIDE 2%

SPIRONOLACTONE 5%

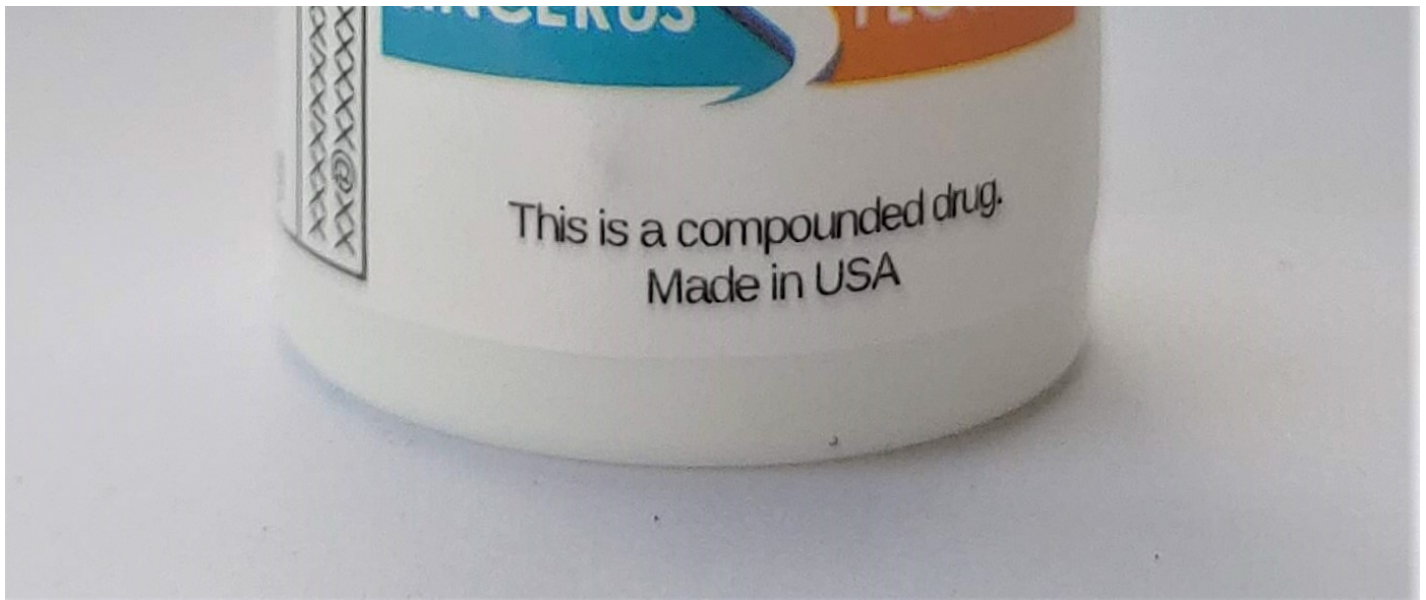
GEL 30gm

Rx only
BUD: XXXXXXXXXX
Active Ingredients

Lot: 011503XXX
MFG: X

SINCERUS

FLORIDA



011503 DAPSONE 6% / NIACINAMIDE 2% / SPIRONOLACTONE 5%

011503 dapsone 6% / niacinamide 2% / spironolactone 5% gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-1211
Route of Administration	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
DAPSONE (UNII: 8W5C518302) (DAPSONE - UNII:8W5C518302)	DAPSONE	6 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1211-2	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
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unapproved drug other

07/02/2020

Labeler - Sincerus Florida, LLC (080105003)

Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-1211)

Revised: 7/2020

Sincerus Florida, LLC