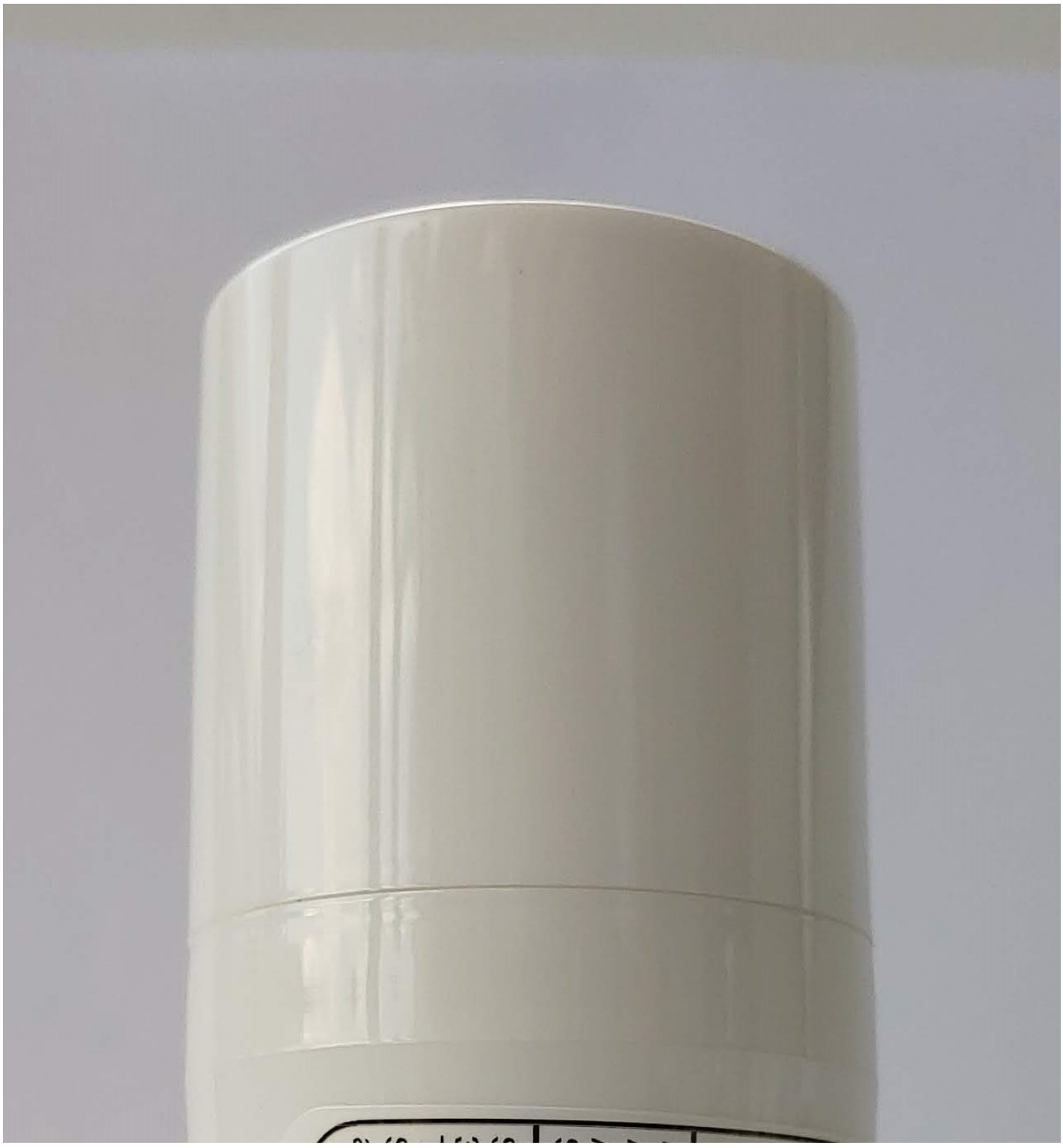
171083 IVERMECTIN 1% / METRONIDAZOLE 1% / NIACINAMIDE 4% - 171083 ivermectin 1% / metronidazole 1% / niacinamide 4% gel
Sincerus Florida, LLC

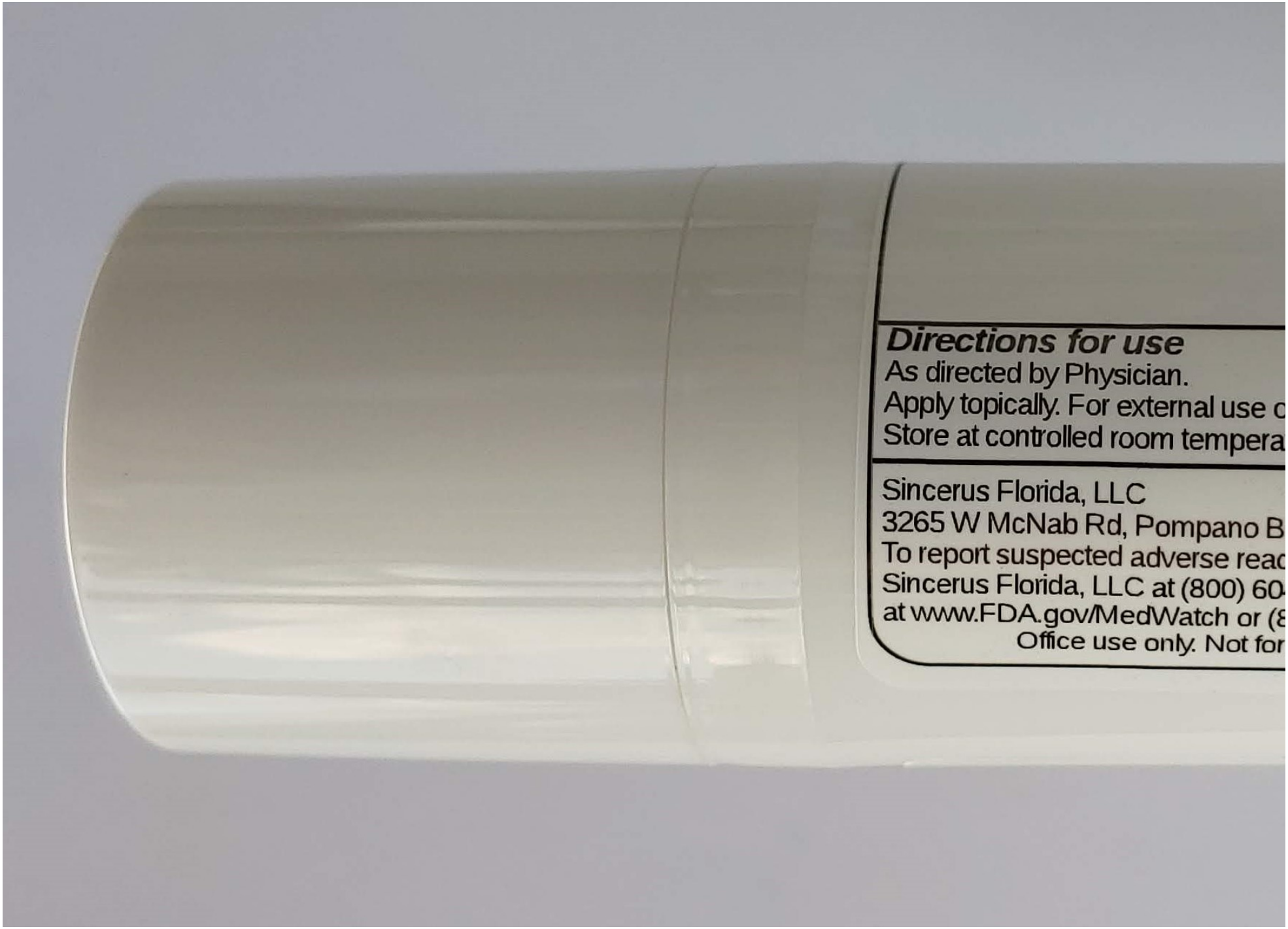
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

171083 IVERMECTIN 1% / METRONIDAZOLE 1% / NIACINAMIDE 4%

Directions for use



Sincerus Florida, LLC adverse reactions


Directions for use
As directed by Physician.
Apply topically. For external use o
Store at controlled room tempera
Sincerus Florida, LLC
3265 W McNab Rd, Pompano B
To report suspected adverse reac
Sincerus Florida, LLC at (800) 60
at www.FDA.gov/MedWatch or (8
Office use only. Not for

Active, inactive

171083
IVERM
METRO
NIACIN
GEL 30

SINC

Rx only Lot: 171083XXXXXXXXX@XX
BUD: XX/XX/XXXX MFG: XX/XX/XXXX

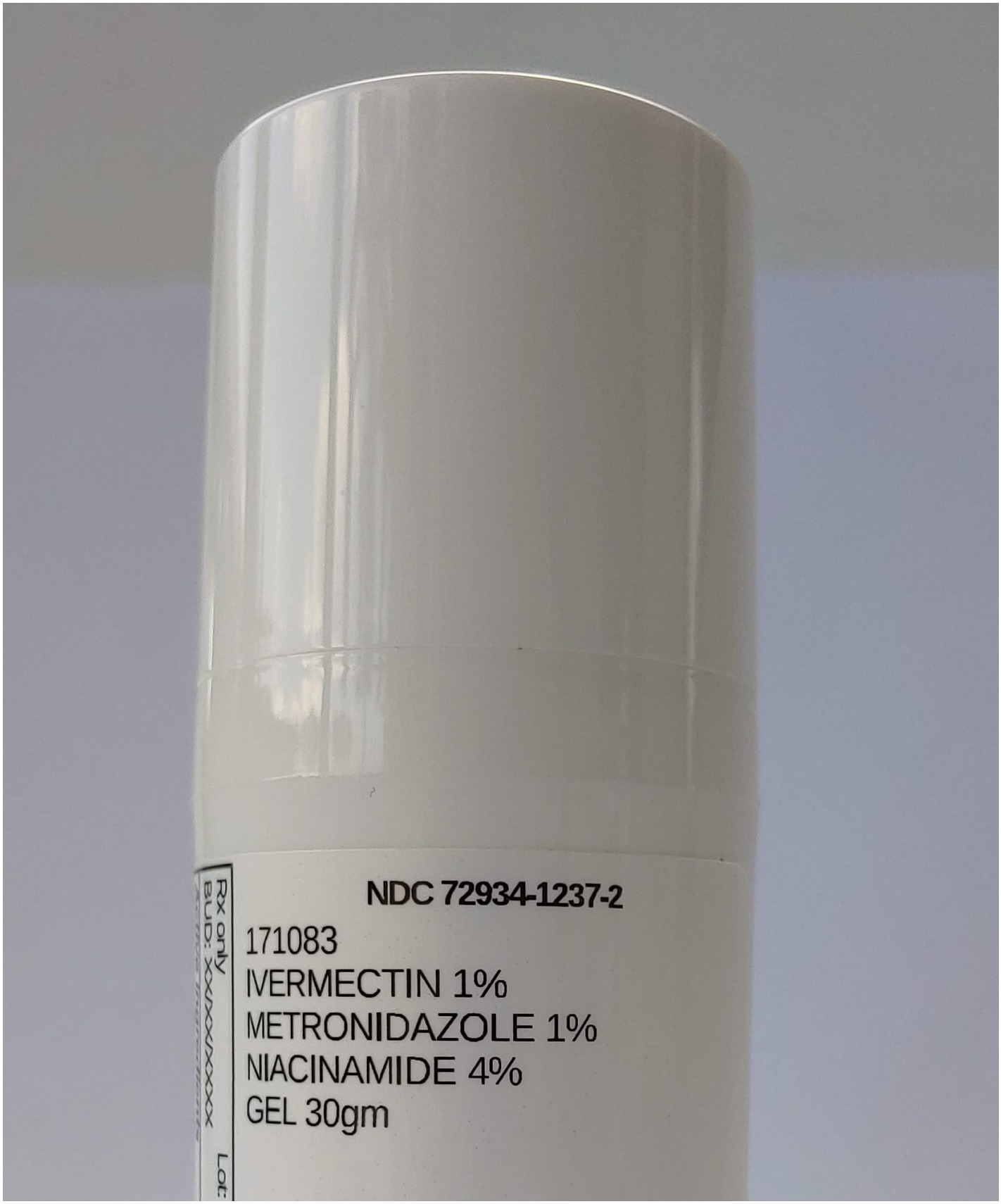
Active ingredients

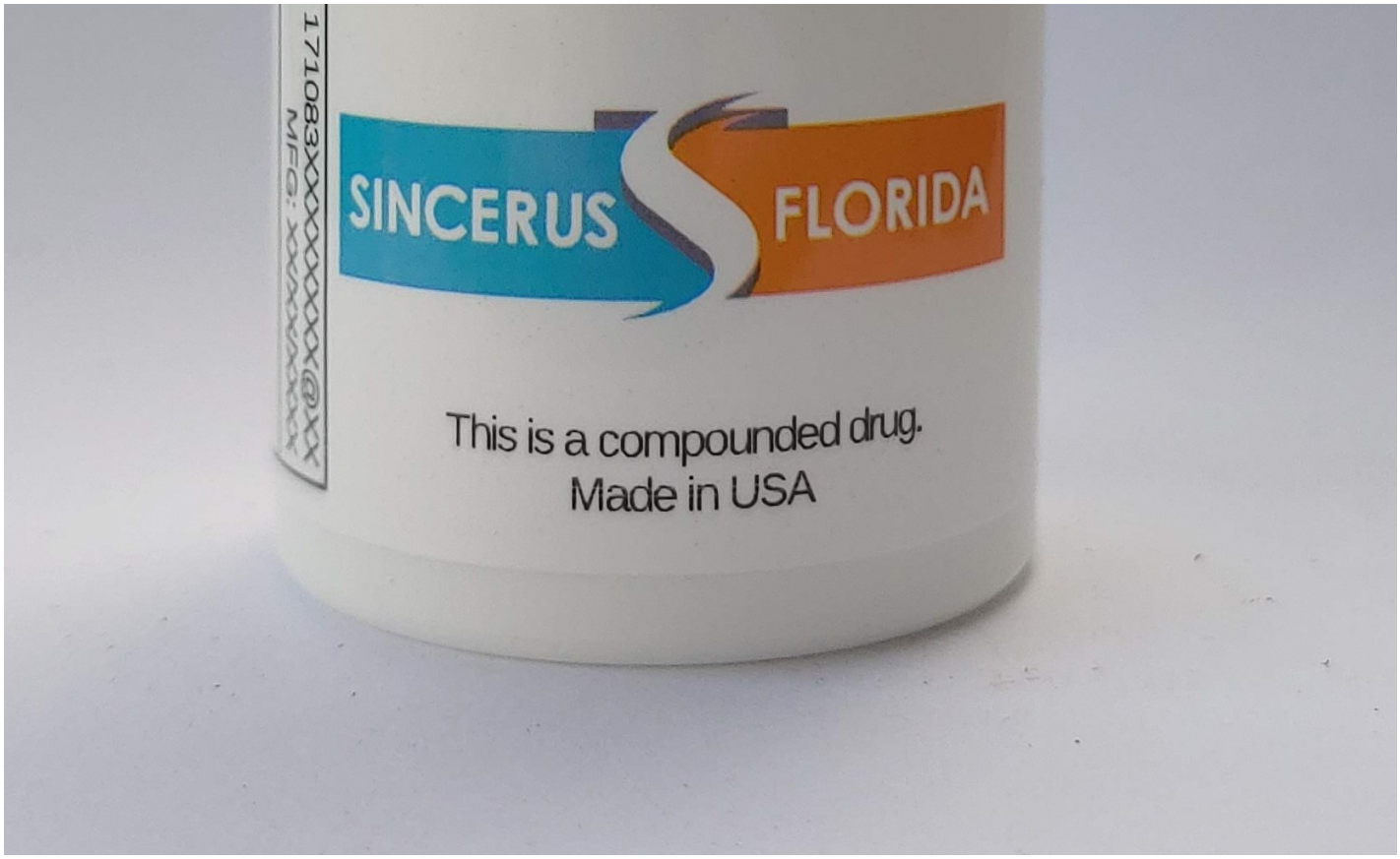
Ivermectin USP (anhydrous)	1%
Metronidazole USP	1%
Niacinamide USP	4%

Inactive ingredients

Butylated Hydroxytoluene NF (BHT)	0.1%
Glycerin USP	2%
Krisgel 100	3%
Potassium Azeloyl Diglycinate 20%	5%
Suspendisse Gel	50%
Suspendisse Silicone Gel	32.4%

NDC 72934-1237-2 171083 IVERMECTIN 1% / METRONIDAZOLE 1% / NIACINAMIDE 4% gel 30 gm





171083 IVERMECTIN 1% / METRONIDAZOLE 1% / NIACINAMIDE 4%

171083 ivermectin 1% / metronidazole 1% / niacinamide 4% gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72934-1237
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METRONIDAZOLE (UNII: 140QMO216E) (METRONIDAZOLE - UNII:140QMO216E)	METRONIDAZOLE	1 g in 100 g
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	4 g in 100 g
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	1 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:72934-1237-2	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(72934-1237)

Revised: 7/2020 Sincerus Florida, LLC