

KETOCONAZOLE 2% / SALICYLIC ACID 2% - ketoconazole 2% / salicylic acid 2% shampoo
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](#).

KETOCONAZOLE 2% / SALICYLIC ACID 2%

Directions for use



Trotamine NF
Zinc Pyritione 50% Dispersion

0.10%
0.49%

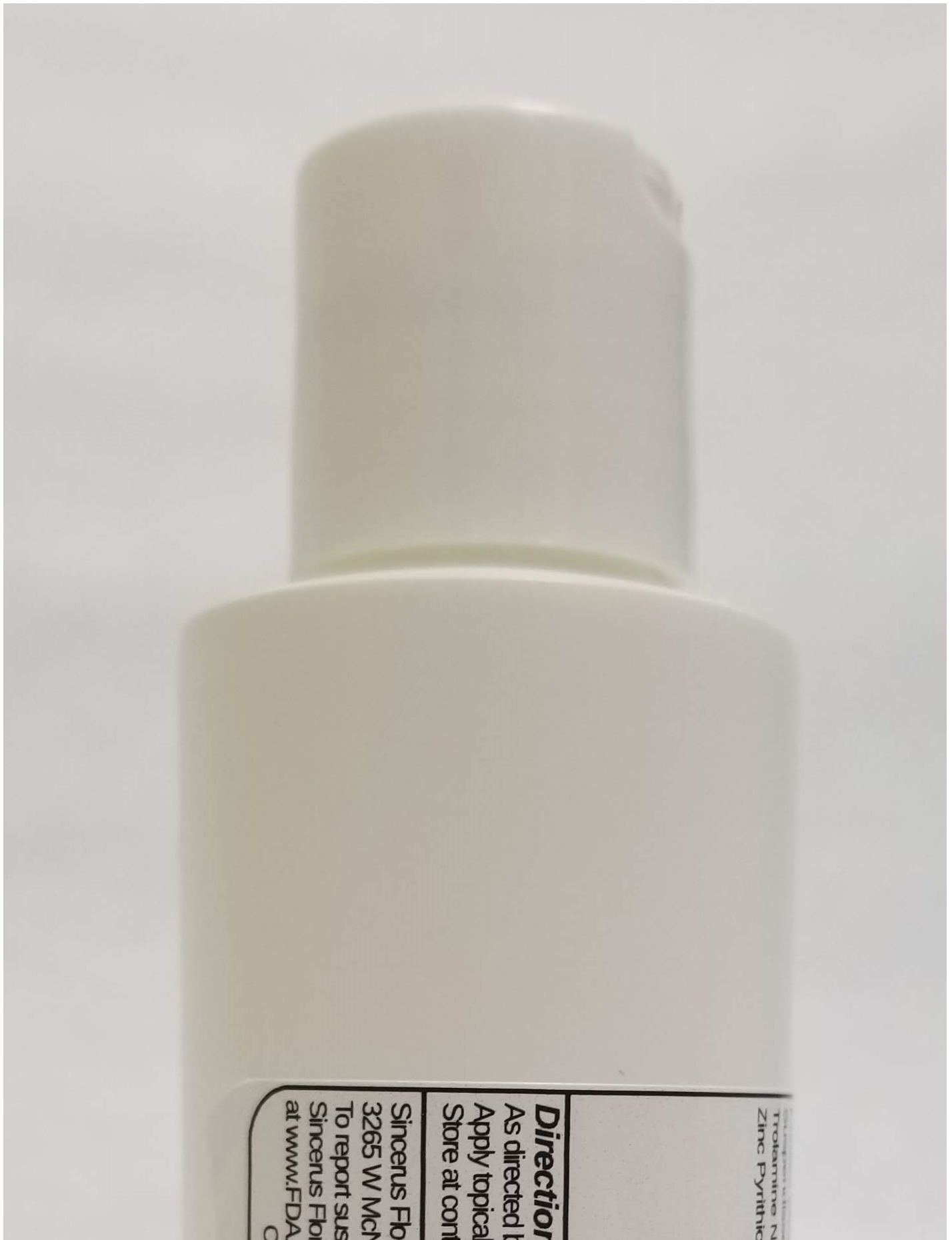
Directions for use

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.



Sincerus Florida, LLC. Adverse reactions



50% Dispersion
0.13%
0.49%

Use for use

by Physician.
ly. For external use only. Wash hands after use.
rolled room temperature (20-25C).

ida, LLC (800) 604-5032
lab Rd, Pompano Beach, FL 33069
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ida, LLC at (800) 604-5032, or FDA
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Active, inactive



KETOCONAZOLE
SALICYLIC ACID
SHAMPOO

Rx only

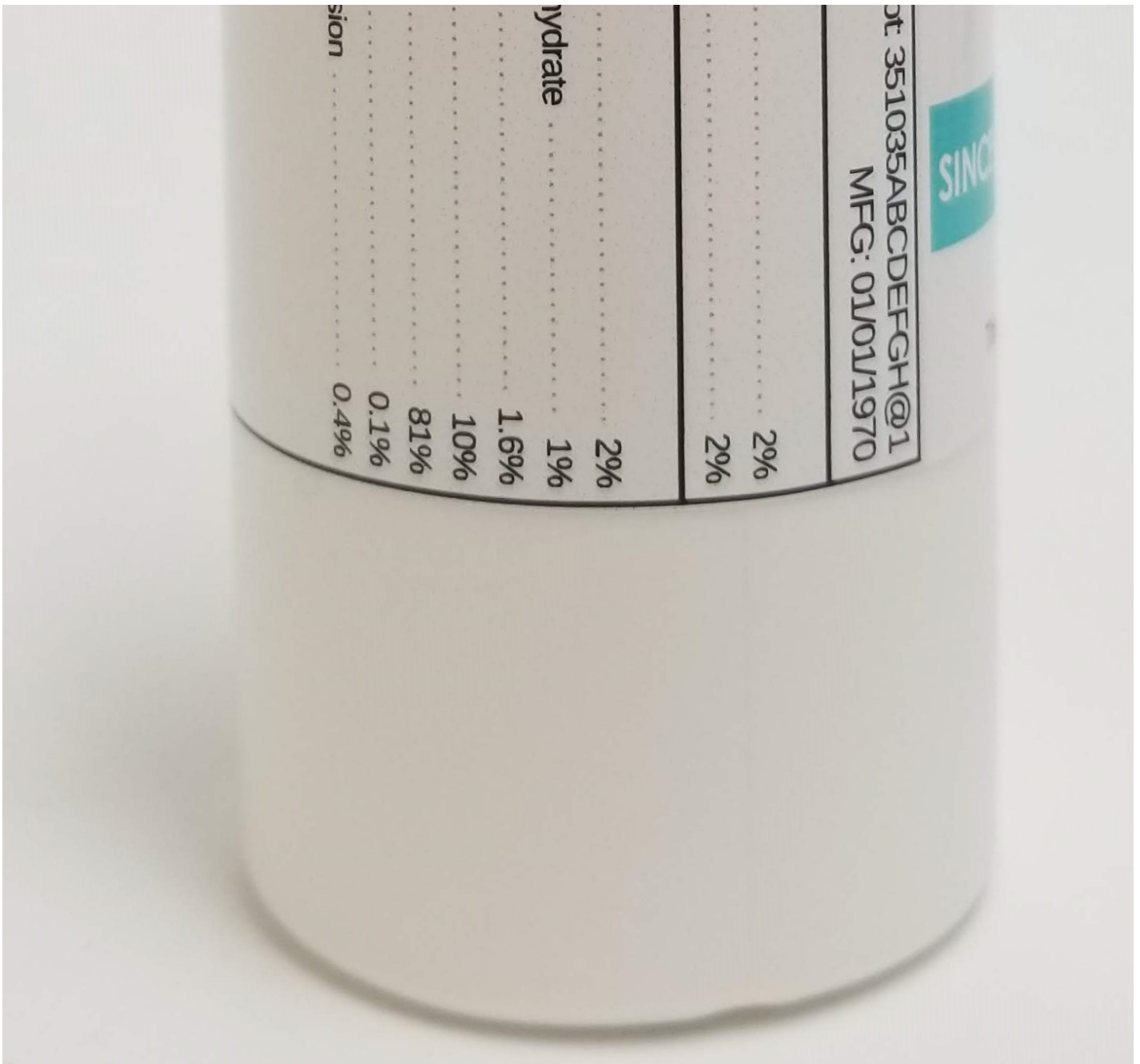
BUD: 01/01/1970

Active ingredients

Ketoconazole USP
Salicylic Acid USP

Inactive ingredients

Cocamide Dea
Edetate Disodium USP Dif
Lactic Acid USP
Purified Water, USP
Suspendisse Shampoo
Trolamine NF
Zinc Pyrithione 50% Dispers



NDC 72934- 7133-6 KETOCONAZOLE USP 2% / SALICYLIC ACID USP 2%. Shampoo 120gm.



NDC 72934-7133-6

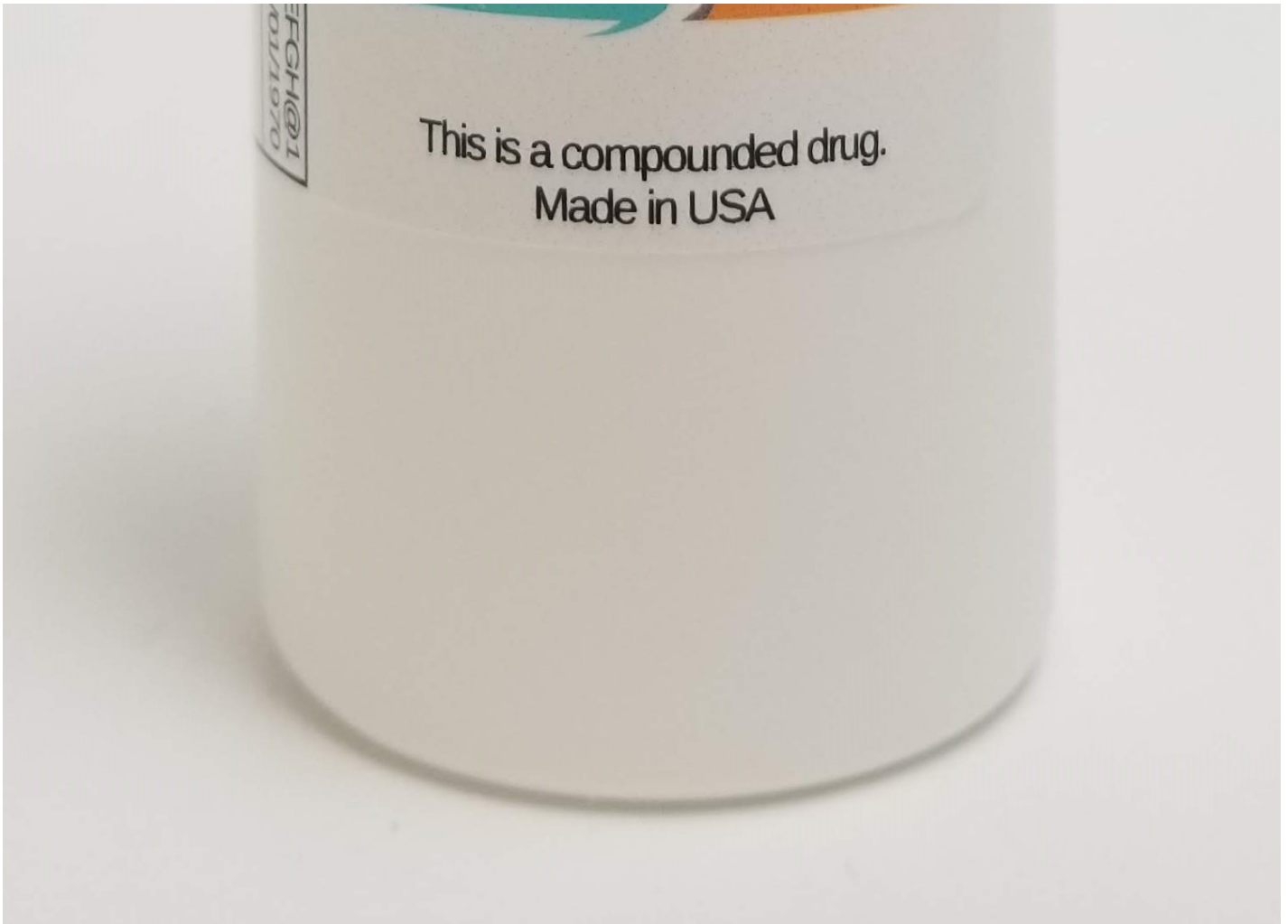
**KETOCONAZOLE USP 2%
SALICYLIC ACID USP 2%
SHAMPOO 120gm**

Rx only
BUD: 01/01/1970

Lot: 351035A
MFG: 01

SINCERUS

FLORIDA



KETOCONAZOLE 2% / SALICYLIC ACID 2%

ketoconazole 2% / salicylic acid 2% shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-7133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	2 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-7133-6	120 g in 1 CYLINDER; Type 0: Not a Combination Product	05/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/17/2019	

Labeler - Sincerus Florida, LLC (080105003)

Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-7133)

Revised: 5/2019

Sincerus Florida, LLC