IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / TRETINOIN 0.05%-
imiquimod 5% / levocetirizine dihydrochloride 1% / 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.

IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / 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.

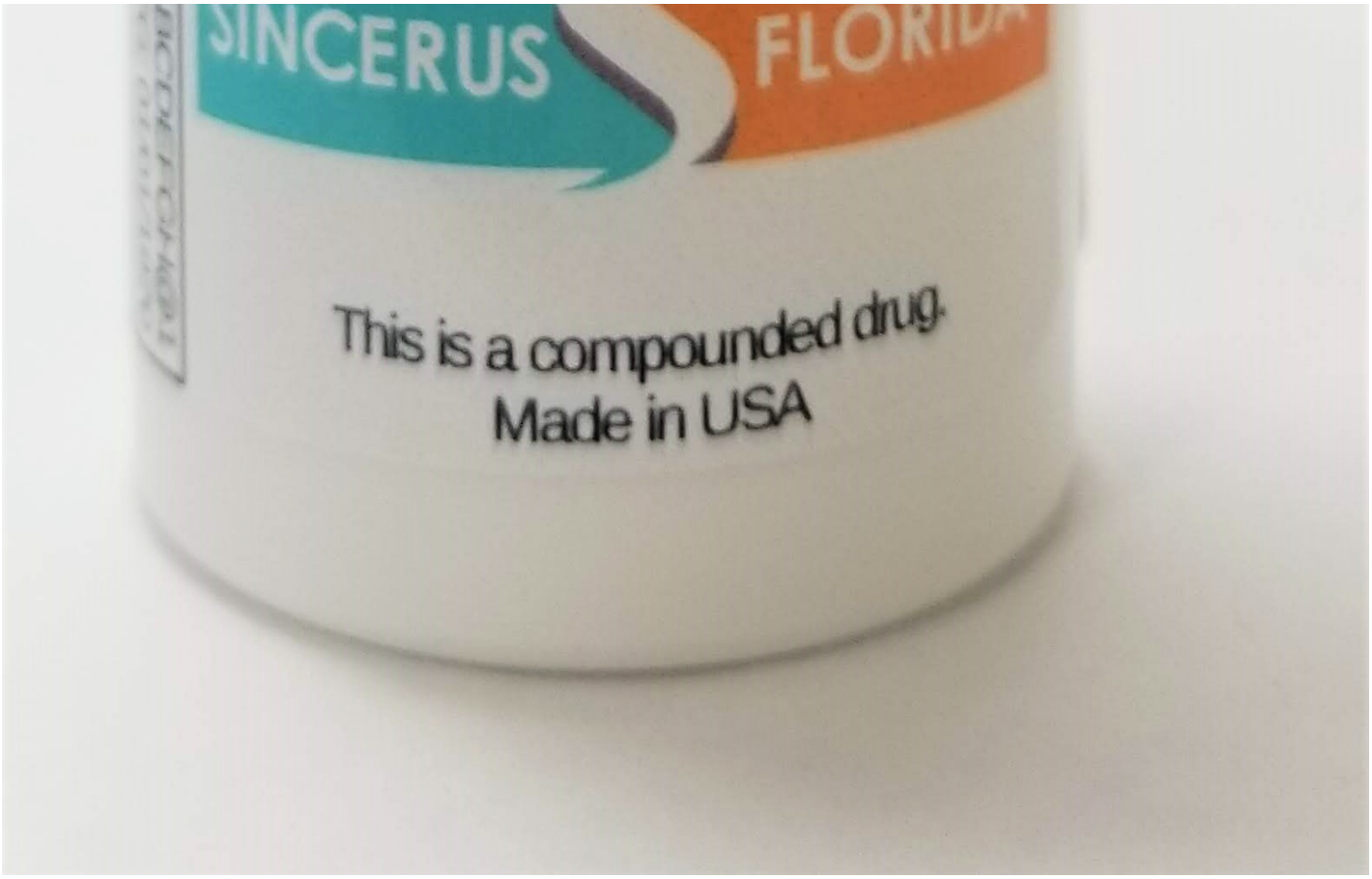
Sincerus Florida, LLC adverse reactions.

Active, inactive


Rx only
BUD: 01/01/1970
Active ingredients
Benzoyl Peroxide USP
Clindamycin Phosphate
Niacinamide USP
Tretinoin USP
Inactive ingredien
Butylated Hydroxytolue
Glycerin USP
Lavender Oil
Sodium Metabisulfite N
Suspendisse Gel

NDC 72934-1011-2
BENZOYL PEROXIDE 2.5 / CLINDAMYCIN PHOSPHATE 1/ NIACINAMIDE 2 / TRETINOIN 0.025
gel 30gm


NDC 72934-1011-2
BENZOYL PEROXIDE USP 2.5%
CLINDAMYCIN PHOSPHATE USP 1%
NIACINAMIDE USP 2%
TRETINOIN USP 0.025%
GEL 30gm



IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / TRETINOIN 0.05%

imiquimod 5% / levocetirizine dihydrochloride 1% / tretinoin 0.05% gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72934-1011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.025 g in 100 g
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 g
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN PHOSPHATE	1 g in 100 g
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	2 GBq 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:72934-1011-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2019	

Labeler - Sincerus Florida, LLC (080105003)

Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-1011)

Revised: 4/2019 Sincerus Florida, LLC