

**LACTIC ACID 10% / UREA 40% - lactic acid 10% / urea 40% 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](#).*

-----

**LACTIC ACID 10% / UREA 40%**

**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](http://www.FDA.gov/MedWatch) or (800) FDA-1088.  
Office use only. Not for resale.





**Sincerus Florida, LLC. Adverse reactions**





**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](http://www.FDA.gov/MedWatch) or (800) FDA-1088.

Office use only. Not for resale.





**Active, Inactive**



LACTIC  
UREA  
GEL

SIN

Rx only  
BUD: 01/01/1970

Lot 2A1019A  
MFG: 01/01/1970

**Active ingredients**

Lactic Acid USP ..... 10%  
Urea USP ..... 40%

**Inactive ingredients**

Aloe Vera ..... 1%  
Caprylic/capric Triglycerides ..... 3%  
Emulsifix ..... 5%  
Krisgel 100 ..... 1%  
Purified Water, USP ..... 40%



**NDC 72934- 1135-4 LACTIC ACID 10% / UREA 40% . Gel 120gm**



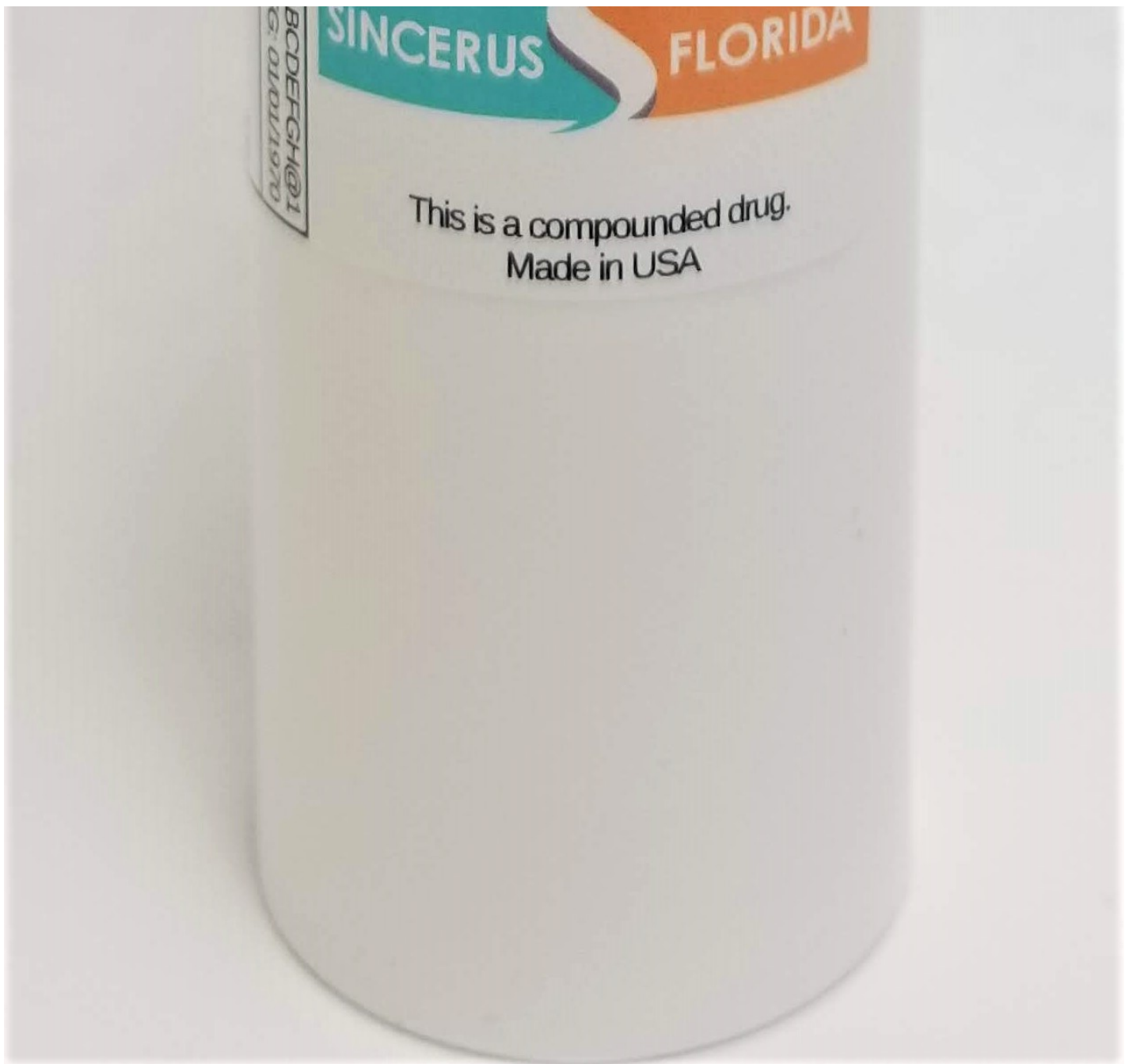


Rx only  
BUD: 01/01/1970  
Active ingredients

Lot 241019A  
MF

**NDC 72934-1135-4**  
**LACTIC ACID USP 10%**  
**UREA USP 40%**  
**GEL 120gm**





## LACTIC ACID 10% / UREA 40%

lactic acid 10% / urea 40% gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72934-1135
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	40 g in 100 g
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	10 g in 100 g

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1135-4	120 g in 1 BOTTLE, PUMP; 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(72934-1135)

Revised: 5/2019

Sincerus Florida, LLC