

HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.05% - hydrocortisone 0.5% / hydroquinone 8% / tretinoin 0.05% emulsion

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](#).

HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.05%

Directions for use



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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



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Sincerus Florida, LLC (800

3265 W McNab Rd, Pompano Beach

To report suspected adverse reactions

Sincerus Florida, LLC at (800) 604-503

at www.FDA.gov/MedWatch or (800) F

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Active, inactive



Rx only BUD: 01/01/1970		Lot 1A1025ABCD EFGH I MFG: 01/01/1970	
Active ingredients			
Hydrocortisone USP	0.5%	
Hydroquinone USP	8%	
Tretinoin USP	0.05%	
Inactive ingredients			
Citric Acid USP Anhydrous	0.2%	
Cyclomethicone	10%	
Dow Corning 1501	2%	
Dow Corning 9011	12%	
Edetate Disodium USP Dihydrate	0.25%	
Emulsifix	2%	
Kojic Acid	4%	
Purified Water, USP	60.3%	
Sodium Chloride USP	0.5%	
Sodium Metabisulfite NF	0.2%	

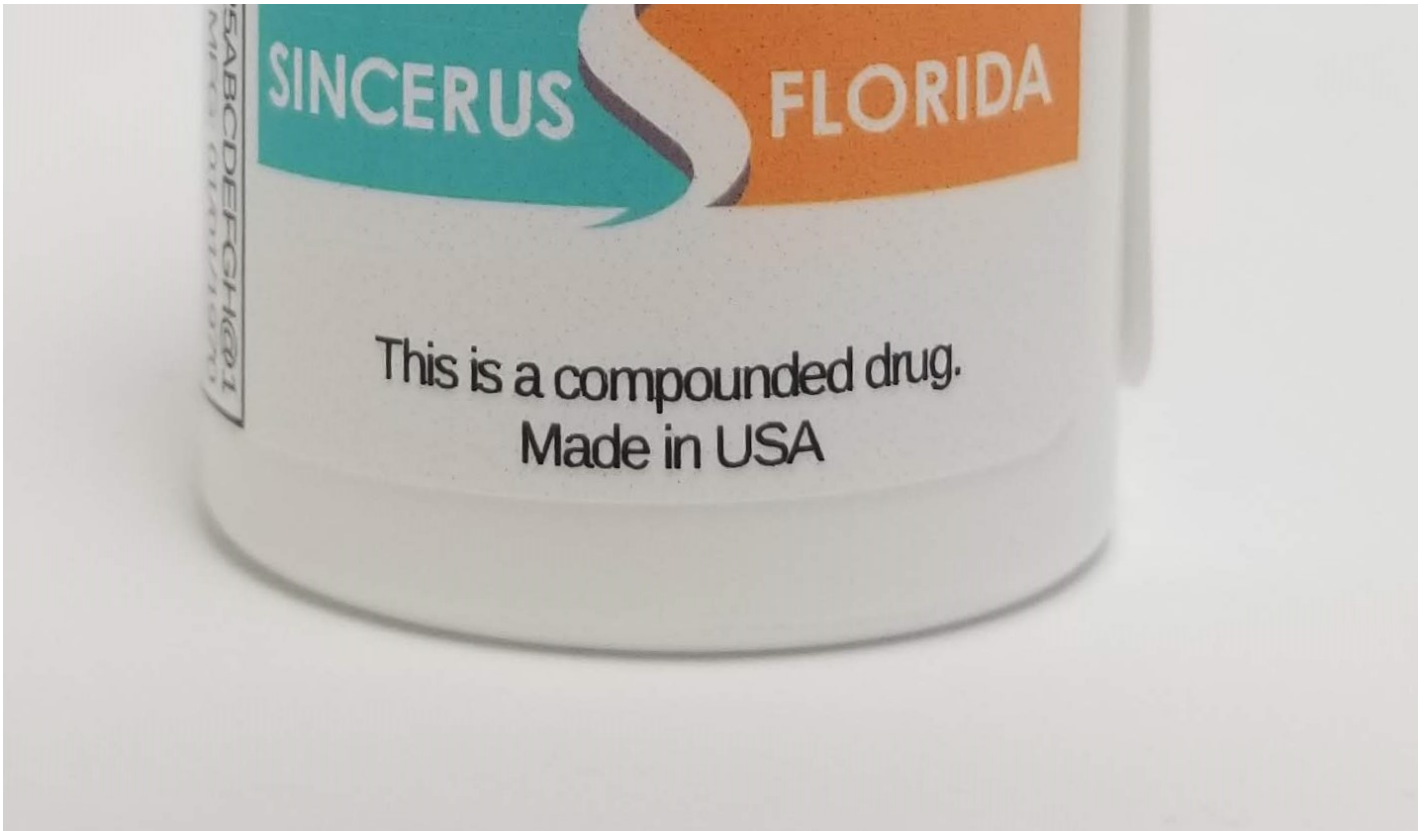
NDC 72934- 6108- HYDROCORTISONE USP 0.5% / HYDROQUINONE USP 8% / TRETINOIN USP 0.05%. Emulsion 30 gm

NDC 72934-6108-2

HYDROCORTISONE USP 0.5%
HYDROQUINONE USP 8%
TRETINOIN USP 0.05%
EMULSION 30gm

Rx ONLY
NDC 72934-6108-2

Lot 14102



HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.05%

hydrocortisone 0.5% / hydroquinone 8% / tretinoin 0.05% emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-6108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.05 g in 100 g
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	0.5 g in 100 g
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	8 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:72934-6108-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/17/2019	
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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(72934-6108)

Revised: 5/2019

Sincerus Florida, LLC