

141061 HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.025% - 141061 hydrocortisone 0.5% / hydroquinone 8% / tretinoin 0.025% 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](#).

141061 HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.025%

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.

LS-01-000000-00



Sincerus Florida, LLC adverse reactions

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Sincerus Florida, LLC

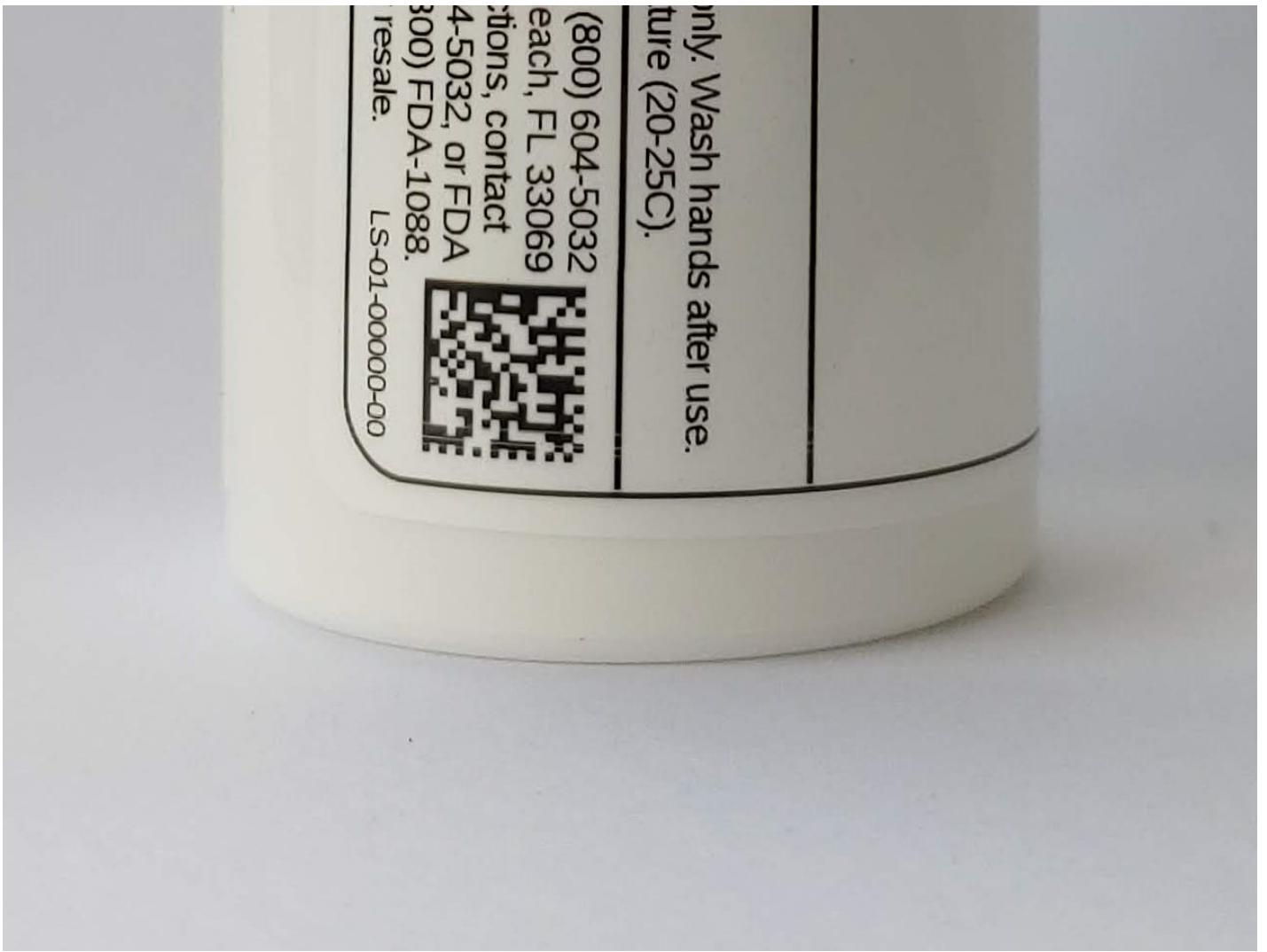
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Sincerus Florida, LLC at (800) 60

at www.FDA.gov/MedWatch or (8

Office use only. Not for



Active, inactive



141061 HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.025% EMULSION
 Rx only Lot: 141061XXXXXXXXXXXX@XXX
 BUD: XXXXXXXXXXXX MFG: XXXXXXXXXXXX

Active ingredients
 Hydrocortisone USP 0.5%
 Hydroquinone USP 8%
 Tretinoin USP 0.025%

Inactive ingredients
 Citric Acid USP Anhydrous 0.2%
 Cyclomethicone 10%
 Dow Corning 1501 2%
 Dow Corning 9011 12%
 Edetate Disodium USP Dihydrate 0.25%
 Kojic Acid 4%
 Purified Water USP 62.325%
 Sodium Chloride USP 0.5%
 Sodium Metabisulfite NF 0.2%

NDC 72934-6233-2 141061 HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.025% emulsion 30 gm

NDC 72934-6233-2

141061

HYDROCORTISONE 0.5%

HYDROQUINONE 8%

TRETINOIN 0.025%

EMULSION 30gm

Rx only
BUD: XXXXXXXXX
Active Ingredients

Lot: 141061XXXXXXXXXX@XX
MFG: XXXXXXXXX



This is a compounded drug.
Made in USA

141061 HYDROCORTISONE 0.5% / HYDROQUINONE 8% / TRETINOIN 0.025%

141061 hydrocortisone 0.5% / hydroquinone 8% / tretinoin 0.025% emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-6233
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	8 g in 100 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.025 g in 100 g
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	0.5 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:72934-6233-2	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(72934-6233)

Revised: 7/2020

Sincerus Florida, LLC