

HYDROCORTISONE 0.5% / HYDROQUINONE 6% - hydrocortisone 0.5% / hydroquinone 6% 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 6%

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



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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

Office use only. Not for resal



Active, inactive



BUO: 01001970

Active ingredients

Hydrocortisone USP 0.5%
Hydroquinone USP 6%

Inactive ingredients

Ascorbyl Palmitate Fcc 2%
Citric Acid USP Anhydrous 0.2%
Cyclomethicone 10%
Dow Corning 1501 2%
Dow Corning 9011 12%
Edetate Disodium USP Dihydrate 0.25%
Green Tea Extract 2%
Kojic Acid 6%
Purified Water, USP 57.35%
Sodium Chloride USP 0.5%
Sodium Metabisulfite NF 0.2%
Vitamin E Acetate USP Liquid 1%

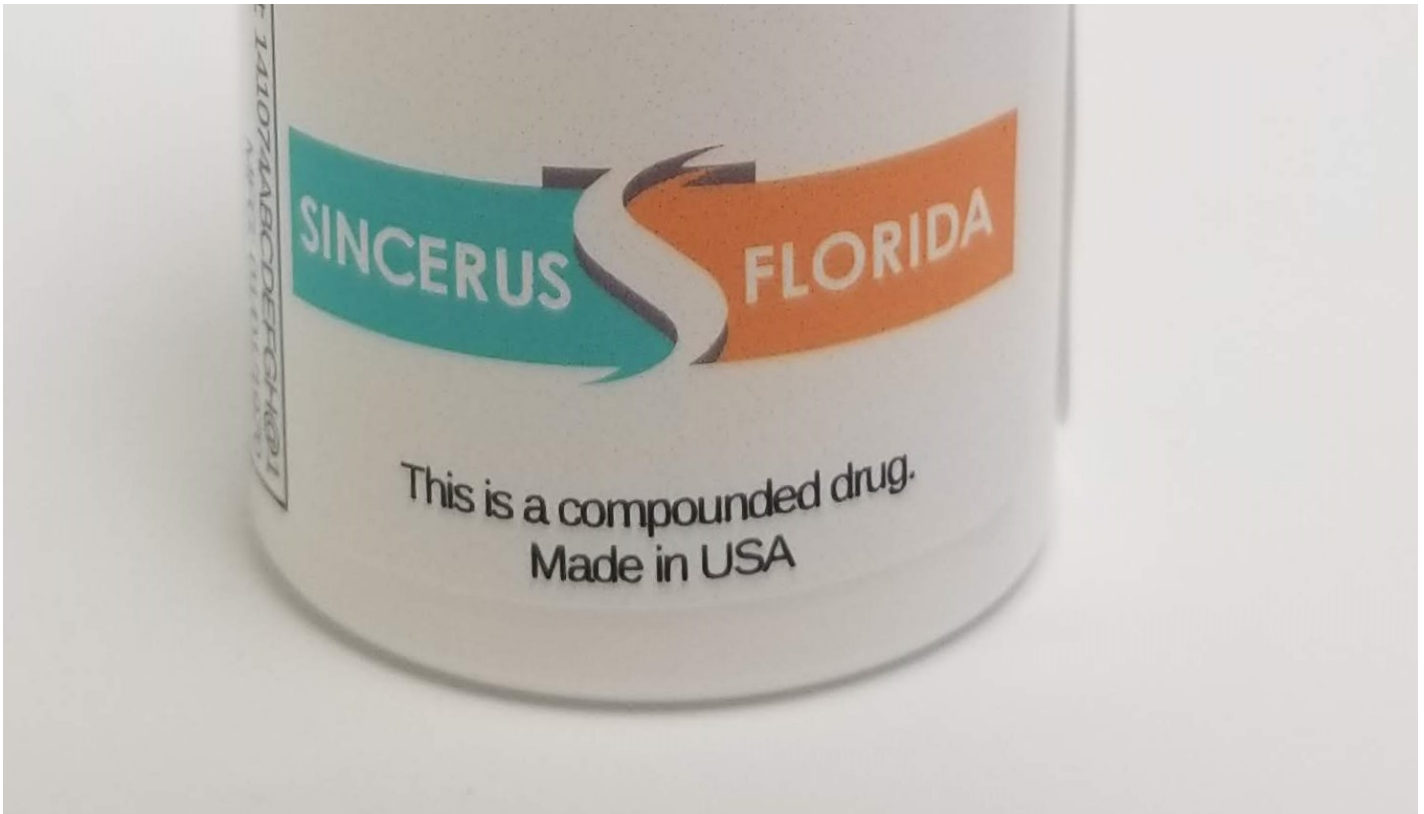
DIRECTIONS: See USP

NDC 72934- 6103-2 HYDROCORTISONE USP 0.5% / HYDROQUINONE USP 6%. Emulsion
30 gm

Rx only
NDC 72934-6103-2
Lot

NDC 72934-6103-2

**HYDROCORTISONE USP 0.5%
HYDROQUINONE USP 6%
EMULSION 30gm**



HYDROCORTISONE 0.5% / HYDROQUINONE 6%

hydrocortisone 0.5% / hydroquinone 6% emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-6103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	0.5 g in 100 g
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	6 g in 100 g

Product Characteristics

Color	yellow (beige)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-6103-2	30 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(72934-6103)

Revised: 5/2019

Sincerus Florida, LLC