

HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025% - hydrocortisone 0.5% / hydroquinone 4% / 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](#).

HYDROCORTISONE 0.5% / HYDROQUINONE 4% / 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.



Sincerus Florida, LLC. Adverse reactions



Directions for use

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Store at controlled room temperature (2

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



Rx only
BUD: 01/01/1970 Lot 1A1057/ABCDEFGHI101
MFG: 01/01/1970

Active ingredients

Hydrocortisone USP 0.5%
Hydroquinone USP 4%
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 66.325%
Sodium Chloride USP 0.5%
Sodium Metabisulfite NF 0.2%

**NDC 72934- 6100-2 HYDROCORTISONE USP 0.5% / HYDROQUINONE USP 4% /
TRETINOIN USP 0.025%. Emulsion 30 gm.**





HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025%

hydrocortisone 0.5% / hydroquinone 4% / tretinoin 0.025% emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-6100
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	4 g in 100 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.025 g in 100 g

Product Characteristics

Color	yellow, yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-6100-2	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 Florda, LLC (080105003)

Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-6100)

Revised: 5/2019

Sincerus Florda, LLC