

**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](#).*

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**HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025%**

**Directions for use**



Kojic Acid  
Purified Water, USP  
Sodium Chloride USP  
Sodium Metabisulfite NF

0.5%  
0.2%

**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.

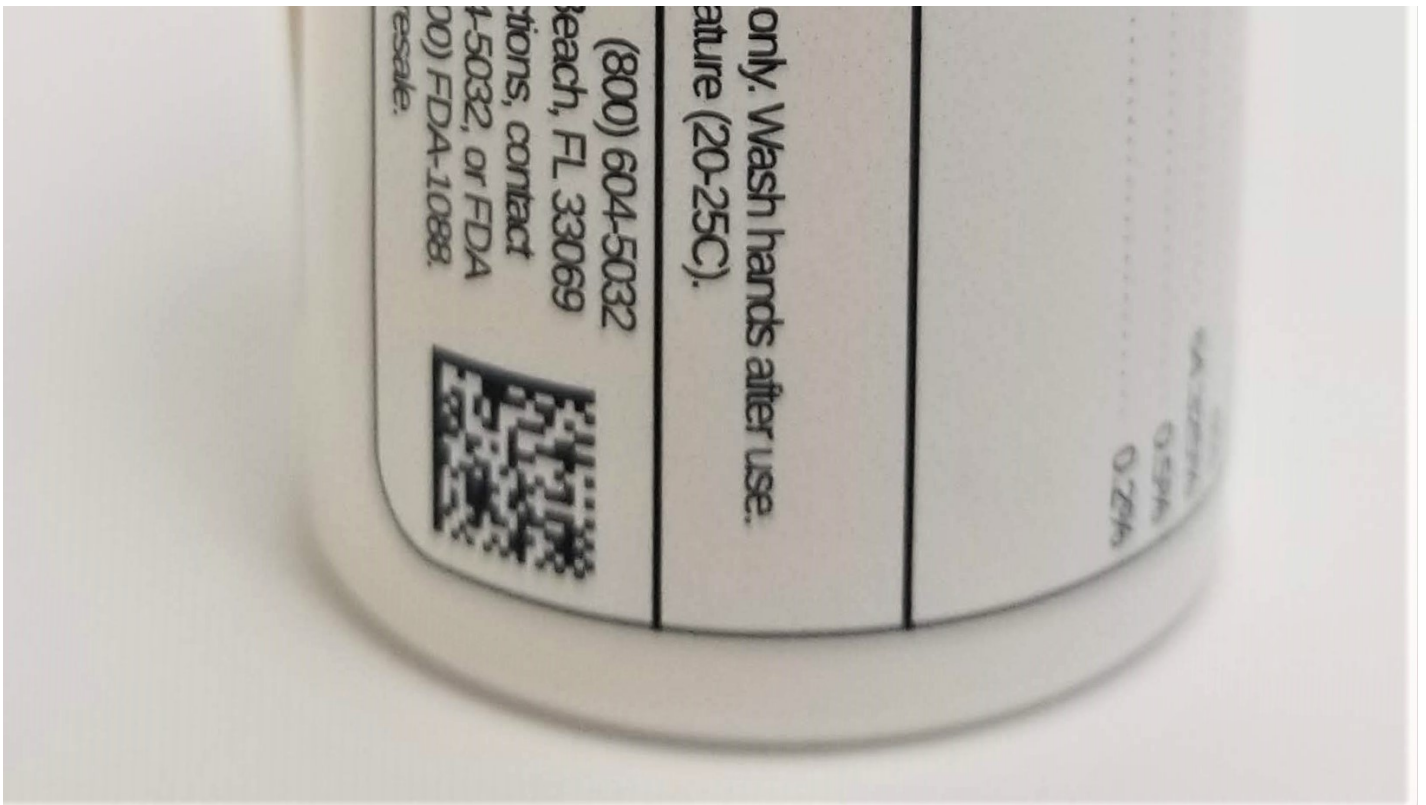


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Office use only. Not for patient use.



**Ative, Inactive**



Rx only  
BUD: 01/01/1970

LOT: 1A107847  
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	6%
Purified Water, USP	64.325%
Sodium Chloride USP	0.5%
Sodium Metabisulfite NF	0.2%

**NDC 72934-6099-2**

**HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025%,  
emulsion 30 gm**



**NDC 72934-6099-2**



**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:72934-6099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

<b>HYDROQUINONE</b> (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	4 g in 100 g
<b>HYDROCORTISONE</b> (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	0.5 g in 100 g
<b>TRETINOIN</b> (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.025 g in 100 g

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-6099-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2019	

**Labeler** - Sincerus Florida, LLC (080105003)

### Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-6099)

Revised: 4/2019

Sincerus Florida, LLC