

**HYDROCORTISONE 2.5% / KETOCONAZOLE 2% - hydrocortisone 2.5% / ketoconazole 2% cream**

**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 2.5% / KETOCONAZOLE 2%**

**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](http://www.FDA.gov/MedWatch) or (800) FDA-1088.  
Office use only. Not for resale.



**Sincerus Florida, LLC. Adverse reactions**



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As directed by Physician.

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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](http://www.FDA.gov/MedWatch) or (800) F

Office use only. Not for resal



**Active, inactive**



HYDRO  
KETOCC  
CREAM

SINCE

Rx only

BUD: 01/01/1970

Lot: 121020ABCDEFGHI

MFG: 01/01/

**Active ingredients**

Hydrocortisone USP

Ketoconazole USP

**Inactive ingredients**

Lipobase Heavy



**NDC 72934- 2112-2 HYDROCORTISONE USP 2.5% / KETOCONAZOLE USP 2% . Cream 30gm.**



**NDC 72934-2112-2**

**HYDROCORTISONE USP 2.5%  
KETOCONAZOLE USP 2%  
CREAM 30gm**

Rx only  
BUD: 01/01/1970

Lot: 121020ABCDEF@1  
MFG: 01/01/1970



This is a compounded drug.  
Made in USA

# HYDROCORTISONE 2.5% / KETOCONAZOLE 2%

hydrocortisone 2.5% / ketoconazole 2% cream

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72934-2112
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	2.5 g in 100 g
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	2 g in 100 g

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-2112-2	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(72934-2112)

Revised: 5/2019

Sincerus Florida, LLC