

**IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / NIACINAMIDE 2% -  
imiquimod 5% / levocetirizine dihydrochloride 1% / niacinamide 2% gel**  
**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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**IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / NIACINAMIDE 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

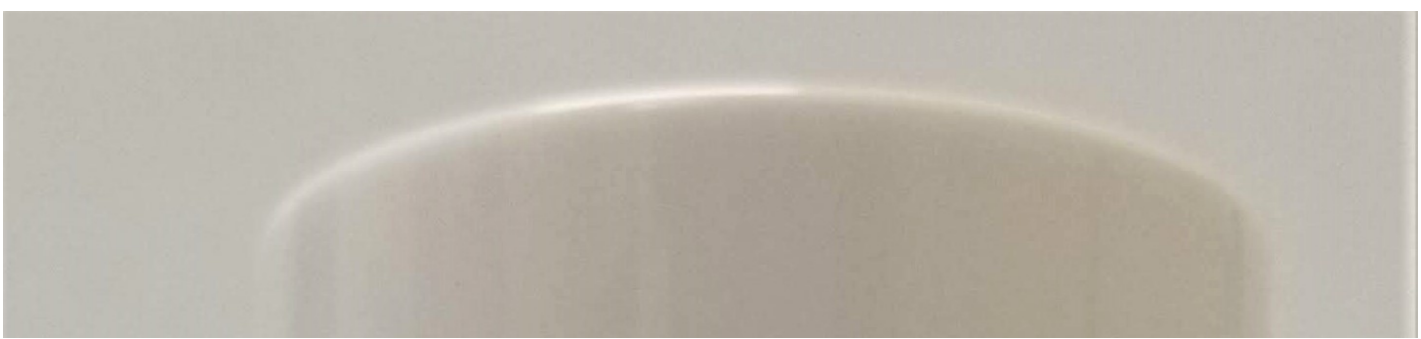
To report suspected adverse reactions, contact

Sincerus Florida, LLC at (800) 604-5032, or FDA  
at [www.FDA.gov](http://www.FDA.gov)/MedWatch or (800) FDA-1088.

Office use only. Not for resale.



Sincerus Florida, LLC adverse reactions.



**Directions for use**

As directed by Physician.

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Store at controlled room temperature

Sincerus Florida, LLC (8

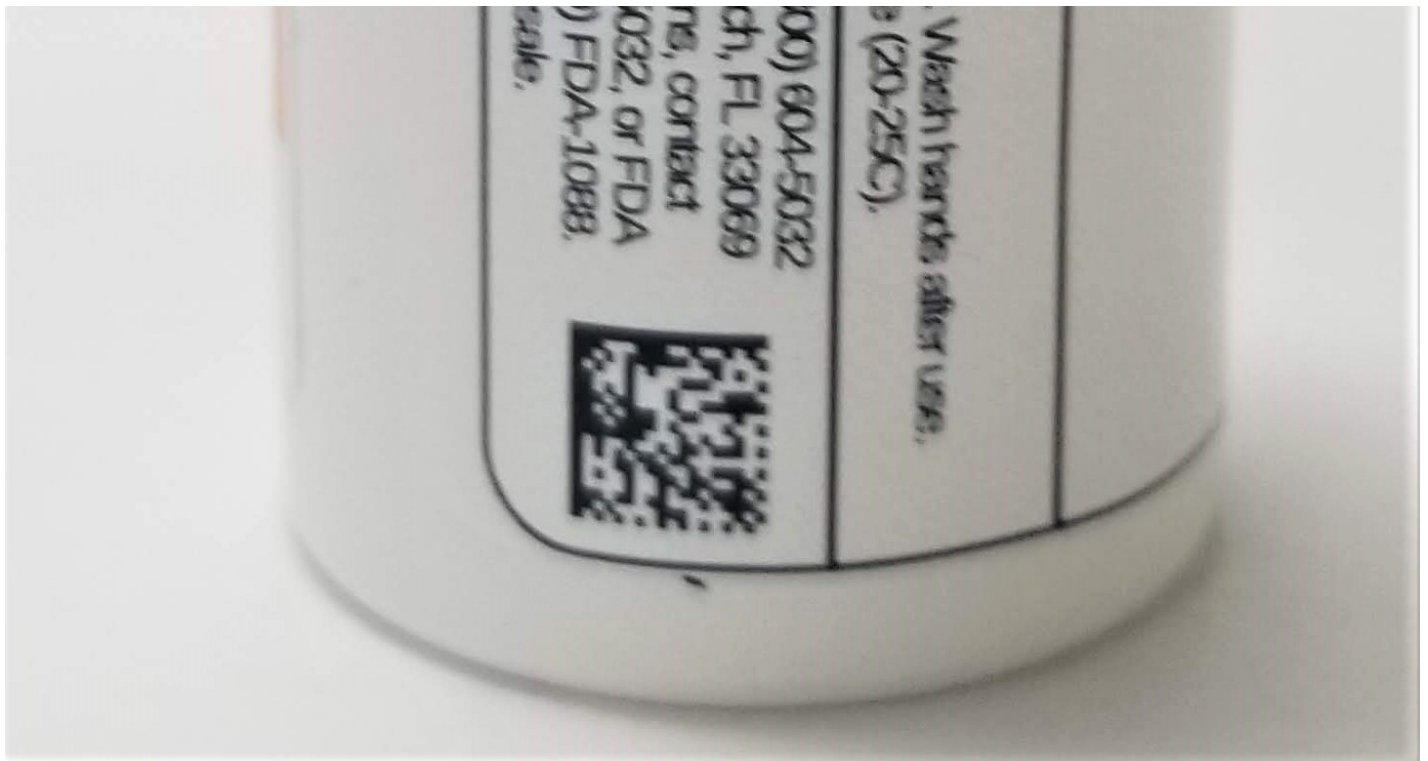
3265 W McNab Rd, Pompano Beach

To report suspected adverse reaction

Sincerus Florida, LLC at (800) 604-5

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

Office use only. Not for re



**Active, Inactive**



IMIQ  
LEV  
DIH  
NAC  
GEL

Rx only

BUD: 01/01/1970

Lot: 021023ABCDEFGHI@1

MFG: 01/01/1970

**Active ingredients**

Imiquimod USP ..... 5  
Levocetirizine Dihydrochloride USP ..... 2  
Niacinamide USP ..... 88

**Inactive ingredients**

Krisgel 100 ..... 2  
Polysorbate 60 NF ..... 88  
Suspendisse Gel ..... 88



**NDC 72934-1125-2 IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / NIACINAMIDE 2%, Gel 30gm**



**NDC 72934-1125-2**

**IMIQUIMOD USP 5%  
LEVOCETIRIZINE  
DIHYDROCHLORIDE USP 1%  
NIACINAMIDE USP 2%  
GEL 30gm**

Rx only  
BUD: 01/01/1970

Lot: 021023ABCDEFCHGHI  
MFG: 01/01/1970



This is a compounded drug.  
Made in USA

**IMIQUIMOD 5% / LEVOCETIRIZINE DIHYDROCHLORIDE 1% / NIACINAMIDE 2%**

imiquimod 5% / levocetirizine dihydrochloride 1% / niacinamide 2% gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72934-1125
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IMIQUIMOD</b> (UNII: P1QW714R7M) (IMIQUIMOD - UNII:P1QW714R7M)	IMIQUIMOD	5 g in 100 g
<b>LEVOCETIRIZINE DIHYDROCHLORIDE</b> (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	1 g in 100 g
<b>NIACINAMIDE</b> (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	2 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1125-2	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(72934-1125)

Revised: 4/2019

Sincerus Florida, LLC