

**FLUOCINOLONE ACETONIDE 0.025% / LIDOCAINE HCL MONOHYDRATE 1% -
fluocinolone acetamide 0.025% / lidocaine hcl monohydrate 1% 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](#).

FLUOCINOLONE ACETONIDE 0.025% / LIDOCAINE HCL MONOHYDRATE 1%

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
As directed by physician.
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Store at controlled room temperature.

Sincerus Florida,
3265 W McNab Road
To report suspected
Sincerus Florida,
at www.FDA.gov
Office

For use
by a healthcare
professional.
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Store at controlled room temperature (20-25C).

LLC (800) 604-5032
10000
Rd, Pompano Beach, FL 33069
For information on
potential
adverse reactions, contact
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FLUCO
USP OI
LIDOCA
MONOH
GEL 60



Rx only
BUD: 01/01/1970

Lot 261019ABCDEFGHI@1
MFG: 01/01/1970

Active ingredients

Fluocinolone Acetonide USP 0.025%
Lidocaine Hydrochloride Monohydrate USP 1%

Inactive ingredients

Charmomile Extract 2%
Krisgel 100 2%
Versapro Gel 89.975%
Witch Hazel USP Extract 5%



**NDC 72934- 1083-3 FLUOCINOLONE ACETONIDE USP 0.025% / LIDOCAINE HCL
MONOHYDRATE USP 1%. Gel 60 gm**



NDC 72934-1083-3

FLUOCINOLONE ACETONIDE

USP 0.025%

LIDOCAINE HYDROCHLORIDE

MONOHYDRATE USP 1%

GEL 60gm



This is a compounded drug.
Made in USA

Rx only
BUD: 01/01/1970
Lot 261019A
MFG: 01/01/1970

FLUOCINOLONE ACETONIDE 0.025% / LIDOCAINE HCL MONOHYDRATE 1%

fluocinolone acetonide 0.025% / lidocaine hcl monohydrate 1% gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-1083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98P200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	1 g in 100 g
FLUOCINOLONE ACETONIDE (UNII: 0CD5FD6S2M) (FLUOCINOLONE ACETONIDE - UNII:0CD5FD6S2M)	FLUOCINOLONE ACETONIDE	0.025 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1083-3	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/20/2019	

Labeler - Sincerus Florida, LLC (080105003)

Establishment			
Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-1083)

Revised: 5/2019

Sincerus Florida, LLC