

IMIQUIMOD 5% / NIACINAMIDE 4% - imiquimod 5% / niacinamide 4% 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](#).

IMIQUIMOD 5% / NIACINAMIDE 4%

Directions for use



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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. Adverse reactions



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Active, inactive



IMIQUIMOD
NIACINAMIDE
GEL 30g

SINCE

Rx only Lot: 021022ABCD EFGH@1
BUD: 01/01/1970 MFG: 01/01/1970

Active ingredients

Imiquimod USP 5%
Niacinamide USP 4%

Inactive ingredients

Glycerin USP 5%
Suspendisse Gel 84%
Tea Tree Oil 2%

NDC 72934-1127-2 IMIQUIMOD USP 5% / NIACINAMIDE USP 4%. Gel 30 gm

Rx only
BUD: 01/01

NDC 72934-1127-2

IMIQUIMOD USP 5%

NIACINAMIDE USP 4%

GEL 30



IMIQUIMOD 5% / NIACINAMIDE 4%

imiquimod 5% / niacinamide 4% gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-1127
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NIACINAMIDE (UNII: 25X51I8 RD4) (NIACINAMIDE - UNII:25X51I8 RD4)	NIACINAMIDE	4 g in 100 g
IMIQUIMOD (UNII: P1QW714R7M) (IMIQUIMOD - UNII:P1QW714R7M)	IMIQUIMOD	5 g in 100 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1127-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/07/2019	

Labeler - Sincerus Florida, LLC (080105003)

Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-1127)

Revised: 5/2019

Sincerus Florida, LLC