IMIQUIMOD 5% / SALICYLIC ACID 30% / TRETINOIN 0.1%- imiquimod 5% / salicylic acid 30% / tretinoin 0.1% 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.

IMIQUIMOD 5% / SALICYLIC ACID 30% / TRETINOIN 0.1%

Directions for use

Sincerus Florida. Adverse reactions

Directions for use

As directed by Physician.

Apply topically. For external use only. W

Store at controlled room temperature (2

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 or (800) F

Office use only. Not for resa

Active, inactive

IMIQ
SALIC
TRET
GEL

Rx only
BUD: 01/01/1970

Lot: 021030ABCDEFGH@1
MFG: 01/01/1970

Active ingredients

Imiquimod USP	5%
Salicylic Acid USP	30%
Tretinoin USP	0.1%

Inactive ingredients

Polysorbate 60 NF	2%
Suspendisse Gel	62.9%

NDC 72934-1128-2 IMIQUIMOD USP 5% / SALICILIC ACID USP 30%/ TRETINOIN USP 0.1%. Gel 30 gm.

IMIQUIMOD 5% / SALICYLIC ACID 30% / TRETINOIN 0.1%

imiquimod 5% / salicylic acid 30% / tretinoin 0.1% gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72934-1128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	30 g in 100 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.1 g in 100 g

IMIQUIMOD (UNII: P1QW714R7M) (IMIQUIMOD - UNII:P1QW714R7M)	IMIQUIMOD	5 g in 100 g

Product Characteristics			
Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-1128-2	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(72934-1128)

Revised: 5/2019 Sincerus Florida, LLC