

**HYALURONIC ACID SODIUM SALT 1% / TACROLIMUS 0.1% / UREA 20% - hyaluronic acid sodium salt 1% / tacrolimus 0.1% / urea 20% 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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**HYALURONIC ACID SODIUM SALT 1% / TACROLIMUS 0.1% / UREA 20%**

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

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**Active, inactive**



HYALURONIC  
SALT 1%  
TACROLIMUS  
USP 0.1%  
UREA  
CREAM



Rx only Lot: 101010A@BCDEFGH@1  
BUD: 01/01/1970 MFG: 01/01/1970

**Active ingredients**

Hyaluronic Acid Sodium Salt ..... 1%  
Tacrolimus Monohydrate USP ..... 0.1%  
Urea USP ..... 20%

**Inactive ingredients**

Suspendisse Cream ..... 78.9%

**WARNING:** Long-term safety of topical calcineurin inhibitors has not been established. Although a causal relationship has not been established, rare cases of malignancy have been reported in patients treated with topical calcineurin inhibitors, including TACROLIMUS cream/injections. Therefore, CONTINUE TO USE OF TOPICAL CALCINEURIN INHIBITORS...

**UREA USP 20%. Cream 30gm.**

Rx only  
BUD: 01/01/1970

**NDC 72934-2097-2**

**HYALURONIC ACID SODIUM  
SALT 1%  
TACROLIMUS MONOHYDRATE  
USP 0.1%  
UREA USP 20%  
CREAM 30gm**





## HYALURONIC ACID SODIUM SALT 1% / TACROLIMUS 0.1% / UREA 20%

hyaluronic acid sodium salt 1% / tacrolimus 0.1% / urea 20% cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72934-2097
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>UREA</b> (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	20 g in 100 g
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH) (HYALURONIC ACID - UNII:S270N0TRQY)	HYALURONATE SODIUM	1 g in 100 g
<b>TACROLIMUS</b> (UNII: WM0HAQ4WNM) (TACROLIMUS ANHYDROUS - UNII:Y5L2157C4J)	TACROLIMUS ANHYDROUS	0.1 g in 100 g

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-2097-2	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(72934-2097)

Revised: 5/2019

Sincerus Florida, LLC