CICLOPIROX 3% / ITRACONAZOLE 5% / UREA 20% - ciclopirox 3% / itraconazole 5% / 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.

CICLOPIROX 3% / ITRACONAZOLE 5% / UREA 20%

Directions for use

Sincerus Florida, LLC. 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

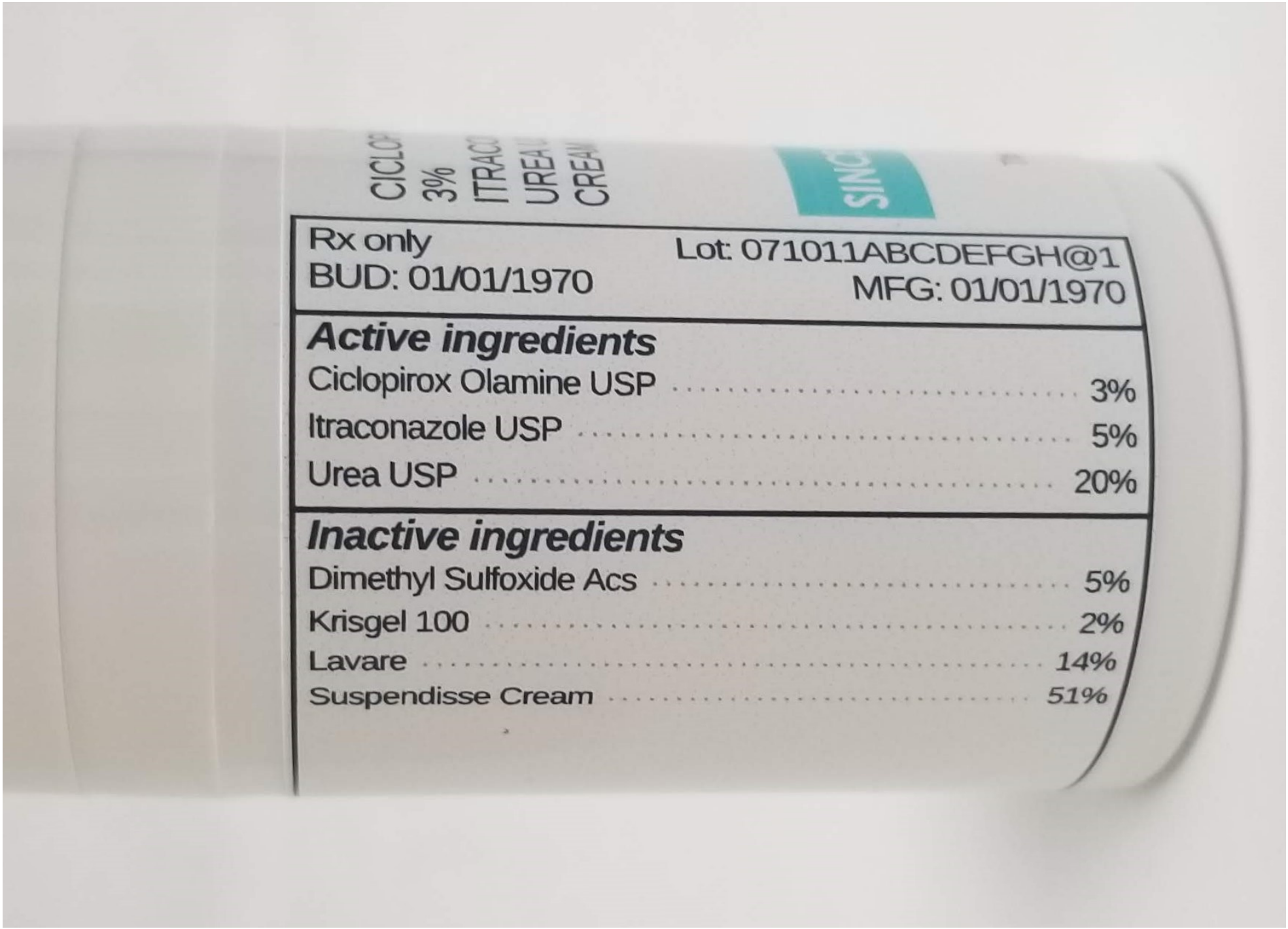
To report suspected adverse reactions

Sincerus Florida, LLC at (800) 604-503

at www.FDA.gov/MedWatch or (800) F

Office use only. Not for resa

Active, inactive


CICLO
3%
ITRACO
UREA
CREA
SING
Rx only
BUD: 01/01/1970
Lot: 071011ABCDEFGH@1
MFG: 01/01/1970
Active ingredients
Ciclopirox Olamine USP 3%
Itraconazole USP 5%
Urea USP 20%
Inactive ingredients
Dimethyl Sulfoxide Acs 5%
Krisgel 100 ..... 2%
Lavare 14%
Suspendisse Cream 51%

NDC 72934- 2044-2 CICLOPIROX 3% / ITRACONAZOLE 5% / UREA 20%. Cream 30 gm

CICLOPIROX 3% / ITRACONAZOLE 5% / UREA 20%

ciclopirox 3% / itraconazole 5% / urea 20% cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72934-2044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CICLOPIROX OLAMINE (UNII: 50MD4SB4AP) (CICLOPIROX - UNII:19W019ZDRJ)	CICLOPIROX	3 g in 100 g

ITRACONAZOLE (UNII: 304NUG5GF4) (ITRACONAZOLE - UNII:304NUG5GF4)	ITRACONAZOLE	5 g in 100 g
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	20 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-2044-2	30 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(72934-2044)

Revised: 5/2019 Sincerus Florida, LLC