

HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025% - hydrocortisone 0.5% / hydroquinone 4% / tretinoin 0.025% emulsion

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](#).

HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025%

Directions for use



Sodium Chloride USP
Sodium Metabisulfite NF
Vitamin E Acetate USP Liquid

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.



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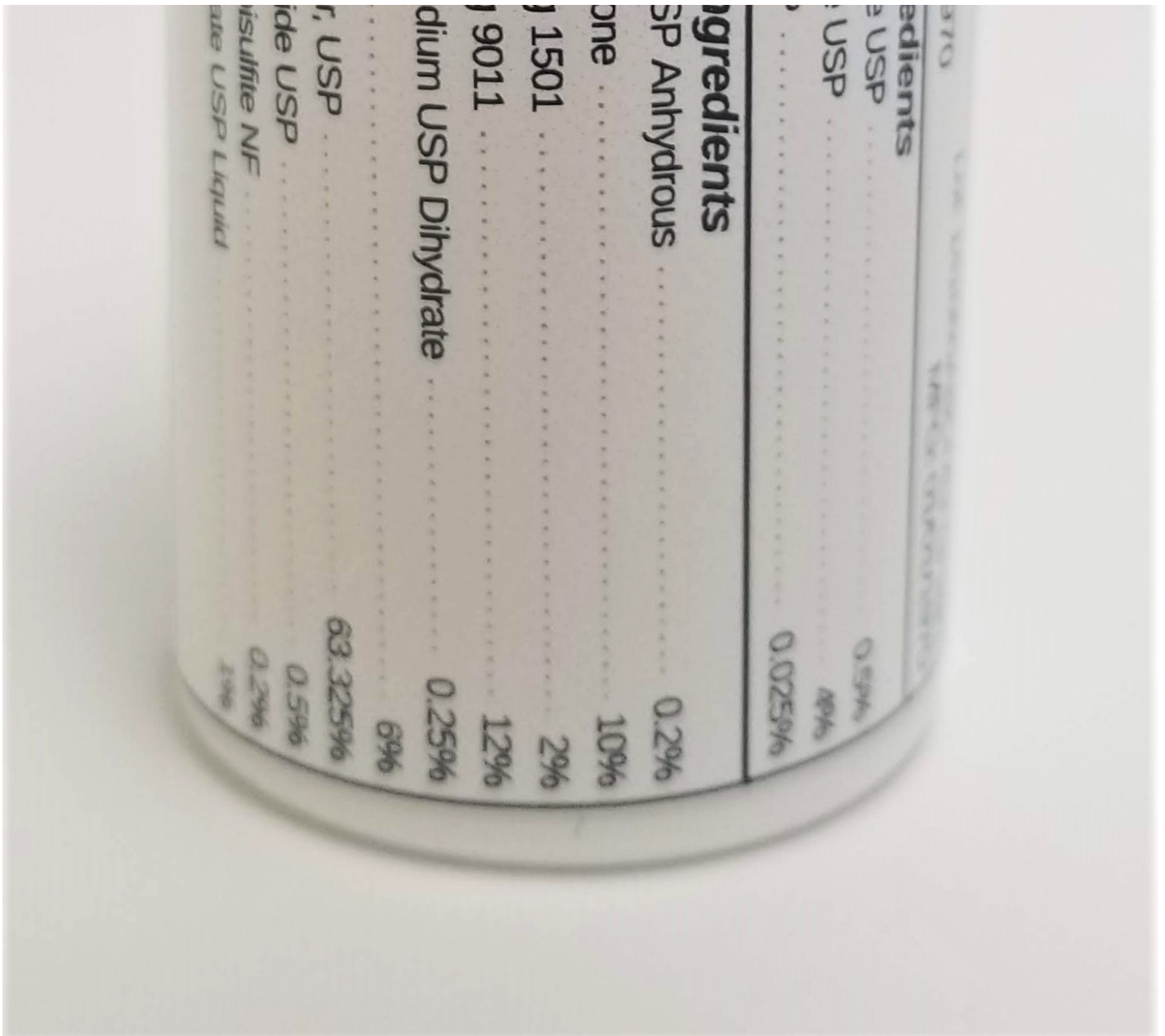
Net wt 1.000g
BUDD: 01/01/15

Active ingredients

- Hydrocortisone
- Hydroquinone
- Tretinoin USP

Inactive ingredients

- Citric Acid US
- Cyclomethicone
- Dow Corning
- Dow Corning
- Edetate Diso
- Kojic Acid
- Purified Water
- Sodium Chloride
- Sodium Metab
- Vitamin E Acetate



NDC 72934-6101-2 HYDROCORTISONE USP 0.5% / HYDROQUINONE USP 4% / TRETINOIN USP 0.025%. Emulsion 30 gm



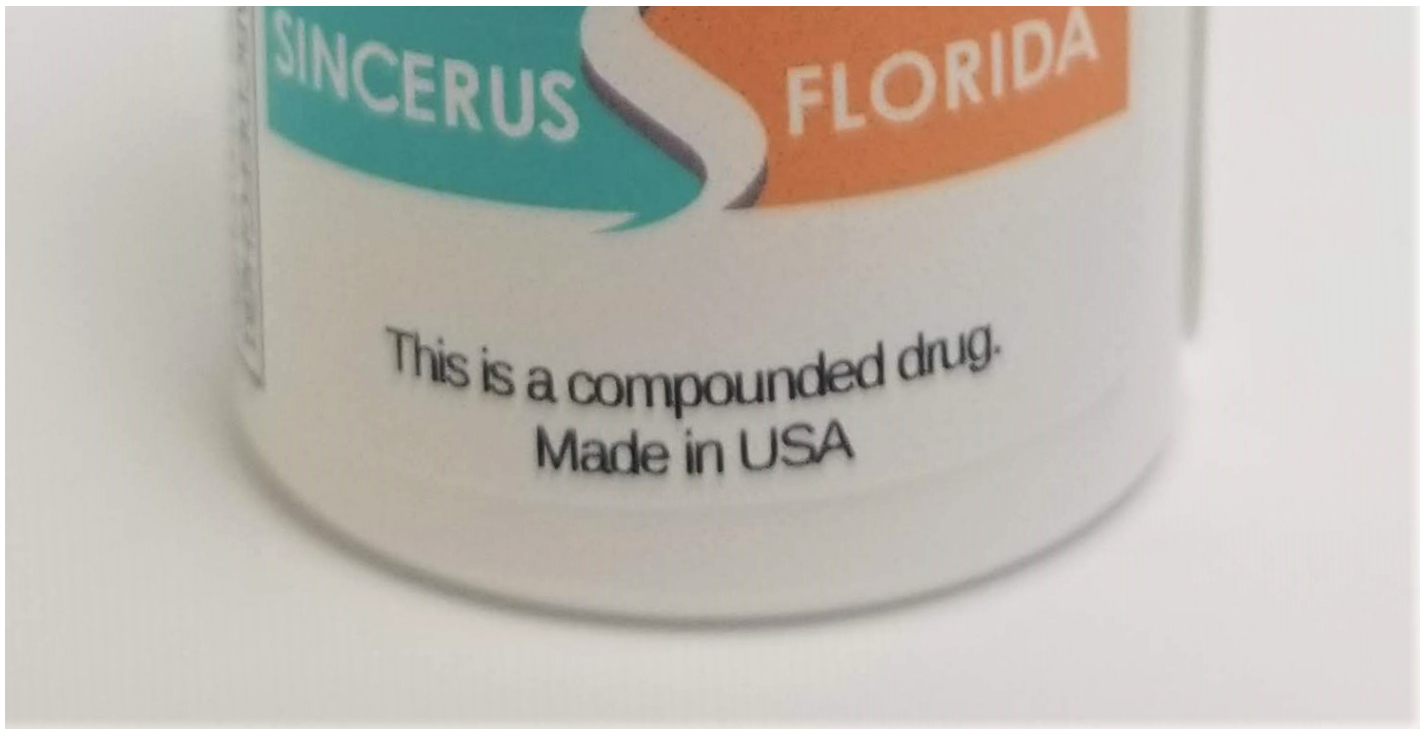
NDC 72934-6101-2

HYDROCORTISONE USP 0.5%

HYDROQUINONE USP 4%

TRETINOIN USP 0.025%

EMULSION 30gm



HYDROCORTISONE 0.5% / HYDROQUINONE 4% / TRETINOIN 0.025%

hydrocortisone 0.5% / hydroquinone 4% / tretinoin 0.025% emulsion

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:72934-6101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ) | HYDROCORTISONE | 0.5 g in 100 g |
| HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE) | HYDROQUINONE | 4 g in 100 g |
| TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R) | TRETINOIN | 0.025 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:72934-6101-2 | 30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/01/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 05/01/2019 | |

Labeler - Sincerus Florida, LLC (080105003)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|-------------------------|
| Sincerus Florida, LLC | | 080105003 | manufacture(72934-6101) |

Revised: 4/2019

Sincerus Florida, LLC