#### CREAM- salicylic acid stick Oxygen Development LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# LIFE BRAND CLEAR ACTION ACNE TREATMENT CONCEALER STICK SALICYLIC ACID ACNE MEDICATION

#### **Directions**

Cleanse skin thoroughly with non-medicated cleanser before applying medication. Apply a thin layer to desired area and gently pat until concealer is blended in. For best results, apply under make-up. Apply 1-3 times daily. If excessive dryness occurs, reduce daily applications, or use as directed by your physician.

#### Warning

For external use only. Use only on non-complex facial acne. Avoid contact with eyes. If contact occurs, immediately flush with water. Do not use with another acne medication, except on the advice of a doctor. If excessive skin irritation develops or increases discontinue use; if irritation persists, consult a doctor.

#### **Medicinal Ingredient**

Salicylic Acid 2% w/w

#### **Non-Medicinal Ingredients**

Octyldodecyl Neopentanoate, Octyldodecanol, Kaolin, Ozokerite, Dipropylene Glycol, Avena Sativa (Oat) Kernel Oil, Hydrogenated Castor Oil, Cetyl Alcohol, Paraffin, Triethoxycaprylylsilane, Phenoxyethanol, Propylparaben, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben. May Contain: Titanium Dioxide, Iron Oxides.

#### Keep out of reach of children.

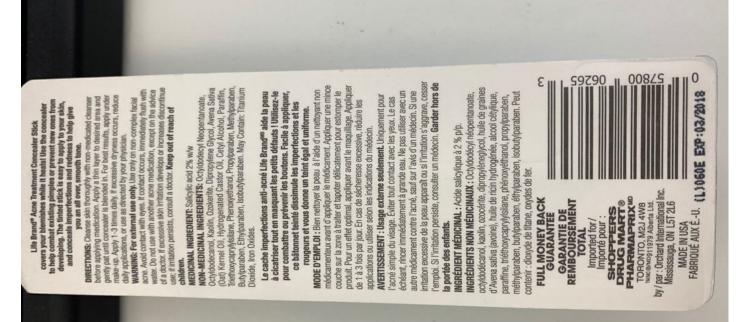
Keep out of reach of children.

Anti-Acne

Use the concealer to help combat existing pimples or prevent new ones from developing.

### Secondary Packaging (Blister)





#### **CREAM**

salicylic acid stick

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:61354-060 Route of Administration TOPICAL

| Active Ingredient/Active Moiety                                      |                          |                |  |
|--|--------------------------|----------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength       |  |
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID           | 2 mg in 100 mg |  |

| Inactive Ingredients                          |          |  |
|---|----------|--|
| Ingredient Name                               | Strength |  |
| CERESIN (UNII: Q1LS2UJO3A)                    |          |  |
| DIPROPYLENE GLYCOL (UNII: E107L85C40)         |          |  |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)    |          |  |
| PARAFFIN (UNII: 1900E3H2ZE)                   |          |  |
| OAT KERNEL OIL (UNII: 3UVP41R77R)             |          |  |
| CETYL ALCOHOL (UNII: 936JST6JCN)              |          |  |
| OCTYLDODECANOL (UNII: 461N1O614Y)             |          |  |
| KAOLIN (UNII: 24H4NWX5CO)                     |          |  |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) |          |  |

| ı | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| 4 | tem Code             | Package Description                                 | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:61354-060-<br>01 | 1 in 1 BLISTER PACK                                 | 02/23/2021              |                       |  |
| 1 |                      | 1.9 mg in 1 TUBE; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | part333D                                    | 02/23/2021              |                       |
|                       |   |                         |                       |

## **Labeler -** Oxygen Development LLC (137098492)

| Establishment          |         |           |                            |  |
|------------------------|---------|-----------|----------------------------|--|
| Name                   | Address | ID/FEI    | Business Operations        |  |
| Oxygen Development LLC |         | 137098492 | api manufacture(61354-060) |  |