**ACNE TREATMENT- dermaline sulfur ointment**
**Dermaline USA corp**

*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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## Dermaline Sulfur

Sulfur Precipitated 10%..... Acne Medication

Uses:

For the treatment of acne. Penetrates the pores and dries and clears pimples and blackheads. Helps to keep new pimples and blackheads from forming.

Warnings: External Use Only. Keep out of reach of children.

Avoid direct contact with eyes. In case of eye contact, flush thoroughly with water. Discontinue use if irritation occurs.

Do not use on wounds or damaged skin, with a bandage, with heating pad, over extensive areas of the body, on children under 16 years of age unless directed by a doctor. If pregnant or breast-feeding ask a health professional before use. In case of accidental ingestion, get medical help or contact a Poison Control center immediately.

Adults and children 16 years of age and older. Wash th affected area with mild soap and warm water and rinse thorougly. Apply to affected area not more than 3 to 4 times daily. Do not bandage tightly or apply to wounds or damaged skin. Children under 16 years of age: consult a doctor.

Cetyl/Stearyl Alcohol, Glycerin, Glyceryl Stearate, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Polyethyleneglycol, Propyleneglycol, Propylparaben, Sorbitan Oleate, Water

Store at controlled room temperature: 15- 30 degrees C (59-86 degree F). Do not expose to excessive heat.

Questions? Dermaline USA, 1(800) 371-0171 Weekdays 9am to 4pm. Eastern

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Acne Medication

Label

# ACNE TREATMENT

dermaline sulfur ointment

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:82165-108 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **SULFUR** (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 10 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **GLYCERYL STEARATE SE** (UNII: FCZ5MH785I) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **PARAFFIN** (UNII: I9O0E3H2ZE) | |
| **PROPYLENE GLYCOL 2-PALMITATE** (UNII: PD789E82CQ) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **PEG-6 SORBITAN OLEATE** (UNII: 58O7V09UCI) | |
| **POLYETHYLENE GLYCOL 300** (UNII: 5655G9Y8AQ) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PETROLATUM** (UNII: 4T6H12BN9U) | |

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

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:82165-108-02 | 70.9 g in 1 JAR; Type 0: Not a Combination Product | 04/15/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | M006 | 04/15/2022 | |

**Labeler -** Dermaline USA corp (016069241)

Revised: 7/2022 Dermaline USA corp