

HONGOSAN DSP- tolnaftate
Dsp Skin Care Products

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.

HONGOSAN DSP KIT

Drug Facts

Active ingredients:

Tolnaftate 1%

Purpose

Antifungal

Keep out of reach of children. If swallowed, get medical help or contact the Poison Control Center

Uses

- *Relieves most external fungal infections.*
- *Relieves most ringworm infections.*
- *Relieves most dermic infections.*
- *Relieves itching, burning, cracking, irritation and scaling.*

Warning- The safety of this product has not been determined. For external use only. Do not use in or near the mouth or eyes. In case of exposure, rinse thoroughly with water.

Directions

Wash the affected area with Hongosan Soap. Dry, and then use the Hongosan Liquid Drops, Wait 5 min., then apply the Hongosan Cream.

Inactive ingredients:

Water, Glycerin, Tea tree oil, Stearic acid, Isopropyl Palmitate, Glycol Stearate, PEG-100 Stearate, Mineral oil, Dimethicone, Petrolatum, Glyceryl Stearate, Phenoxyethanol, Cetyl alcohol, Methylparaben, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Disodium EDTA, Stearamide AMP, Cedrol and Hydroxyethyl Urea.

With Tea Tree Oil

ONLY ONE ANTI-BACTERIAL ACTION

PREMIUM PLUS

ANTI-FUNGAL ANTI-INFECTIOUS - PROTECTOR

3-Piece Set

(Cream, Anti-septic Liquid and Soap)

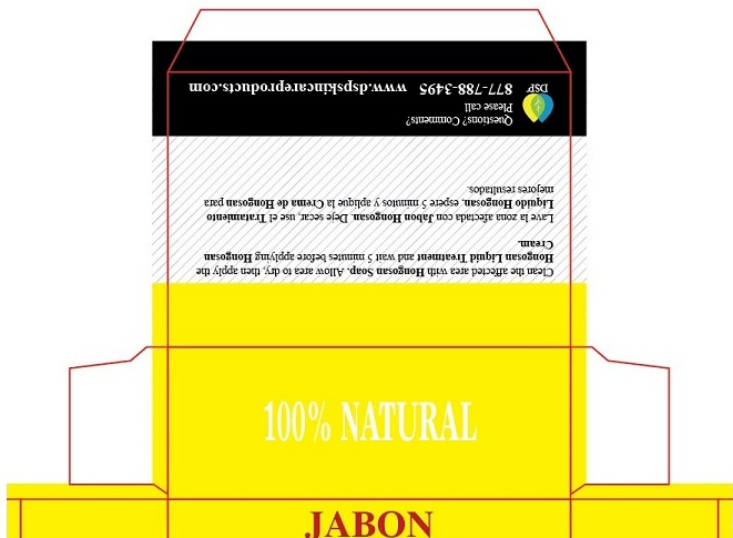
Manufactured by:
DSP Skin Care Products
Los Angeles, CA 90057
1-844-389-2366

Packaging

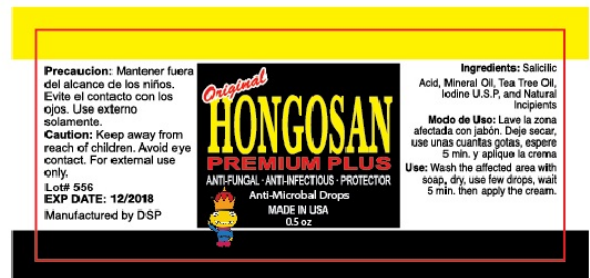
Hongosan DSP Set Box



Hongosan DSP Soap Box



Drops Sticker



Cream Sticker





HONGOSAN DSP

tolnaftate kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70826-576 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70826-576-07 | 1 in 1 KIT; Type 0: Not a Combination Product | 07/09/2016 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|-------------------|------------------------|
| Part 1 | 1 JAR | 56.7 g |
| Part 2 | 1 BOTTLE, DROPPER | 14.8 mL |
| Part 3 | 1 BOX | 1 |

Part 1 of 3

HONGOSAN DSP CREAM

tolnaftate cream

Product Information

| | |
|--------------------------------|---------------|
| Item Code (Source) | NDC:70826-577 |
| Route of Administration | TOPICAL |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) | TOLNAFTATE | 10 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| GLYCOL STEARATE (UNII: 0324G66D0E) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| STEARAMIDE AMP (UNII: U3K8640346) | |
| CEDROL (UNII: 63ZM9703BO) | |
| HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70826-577-02 | 56.7 g in 1 JAR; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C | 07/09/2016 | |

Part 2 of 3

HONGOSAN DSP DROPS

cleansing (cold creams, cleansing lotions, liquids, and pads)

Product Information

Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|-----------------|-----------------------------------|----------|
| INGR | IODINE (UNII: 9679TC07X4) | |
| INGR | SALICYLIC ACID (UNII: O414PZ4LPZ) | |

| | | |
|------|---------------------------------|--|
| INGR | MINERAL OIL (UNII: T5L8T28FGP) | |
| INGR | TEA TREE OIL (UNII: VIF565UC2G) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 14.8 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | | |

Part 3 of 3

HONGOSAN DSP SOAP

bath soaps and detergents

Product Information

Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|-----------------|--|----------|
| INGR | GLYCERIN (UNII: PDC6A3C0OX) | |
| INGR | WATER (UNII: 059QF0KO0R) | |
| INGR | FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| INGR | FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| INGR | CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| INGR | SODIUM BENZOATE (UNII: OJ245FE5EU) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 1 in 1 BOX; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C | 07/09/2016 | |

Labeler - Dsp Skin Care Products (070967913)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|-----------------------------------|
| Dsp Skin Care Products | | 070967913 | manufacture(70826-576, 70826-577) |

Revised: 7/2016

Dsp Skin Care Products