**POISON OAK AND IVY- hydrocortisone, phenol gel**
**DeMartini Spring Hill Pharmacy, Inc.**

*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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HYDROCORTISONE (1%)

PHENOL (0.538%)

PURPOSE

EXTERNAL ANALGESIC

ASTRINGENT

USES: POISON OAK, POISON SUMAC, POISON IVY, MOSQUITO BITES, OTHER ALLERGIC RASHES.

WARNINGS: FOR EXTERNAL USE ONLY. DO NOT USE ON EEP OR PUNCTURE WOUNDS, ANIMAL BITES, OR SERIOUS BURNS.

KEEP OUT OF REACH OF CHILDREN. IN CASE OF OVERDOSE, GET MEDICAL HELP ORCONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS FOR USE: APPLY DIRECTLY TO THE RASH AREA 3 TO 5 TIMES DAILY OR AS NEEDED FOR THE RELIEF OF ITCHING, REDNESS OR WEEPING.

INACTIVE INGREDIENTS: SD Alcohol 40-B, Aqua, Witch Hazel Distillate, Alcohol (Ethanol-Natural Grain USP), Acrylates/C10-30, Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, *CO Aloe Vera Leaf Powder, Citrus Limon (Lemon) Peel Oil, Benzyl Alcohol, Blue 1 *CO certified organic

When using this product
• Avoid getting in eyes or mucus membranes. If contact occurs rinse thoroughly with water.
• Discontinue use if allergic to any of the components.

Stop use and ask a doctor if
• condition worsens
• symptoms last more than 7 days or clear up and occur again within a few days.

If pregnant or breast feeding, ask a health professional before use.



**POISON OAK AND IVY**

hydrocortisone, phenol gel

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:57479-102 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **HYDROCORTISONE** (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE | 1.3 g in 103 mL |
| **PHENOL** (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV) | PHENOL | 0.54 g in 103 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)** (UNII: 71DD5V995L) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **BENZYL ALCOHOL** (UNII: LKG8494WBH) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **LEMON JUICE** (UNII: AGN709ANTJ) | |
| **WITCH HAZEL** (UNII: 101I4J0U34) | |
| **AMINOMETHYL PROPANEDIOL** (UNII: CZ7BU4QZJZ) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:57479-102-01 | 103 mL in 1 TUBE; Type 0: Not a Combination Product | 08/24/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 08/24/2023 | |

## Labeler - DeMartini Spring Hill Pharmacy, Inc. (038273603)

## Registrant - DeMartini Spring Hill Pharmacy, Inc. (038273603)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Spa de Soleil | | 874682867 | manufacture(57479-102) |