ACNE TREATMENT PADS- salicylic acid patch Shanghai Weierya Daily Chemicals Factory

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.

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses for the treatment of acne

Warnings

For external use only.

Avoid contact with eyes & lip, if contact occurs, flush throughly with water.

Ask a doctor or pharmacist before using

other topical acne medications at the same time or immediately following use of this product. May increase dryness or irritation of the skin. If this occurs, only one medication should be usedunless directed by a doctor.

When using this product apply to affected

area only. Do not use on broken skin or apply to large areas of the body.

Keep out of reach of children. If

swallowed, get medical help or contact a Poison Control Center right away.

Directions

- -Cleanse the skin thoroughly before applying medication
- -Use the pad to wipe the entire affected area one to three times daily
- -If bothersome dryness or peeling occurs, reduce application to once a day or every other day
- -Do not peave pad on skin for an extended period of time.

Other information store at room

temperature 68 - 86 F (20 - 30 C)

Inactive ingredients water, SD

alcohol, glycerin, trideceth - 8,

PEG-12 dimethicone, hamamelis virginiana

flower (witch hazel) water, disodium EDTA,

 $benzal konium\,chloride,\,sodium\,hydroxide,\\fragrance$

23.3cm



ACNE TREATMENT PADS

salicylic acid patch

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58194-044 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 2 g in 100 mL | |

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| WATER (UNII: 059QF0KO0R) | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| TRIDECETH-8 (UNII: FZH06801NX) | | | |
| PEG-12 DIMETHICO NE (UNII: ZEL54N6 W95) | | | |
| HAMAMELIS VIRGINIANA FLOWER WATER (UNII: 222MYC9QUV) | | | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C86K) | | | |
| BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) | | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | | |

| Packaging | | | | |
|-----------|------------------|--|-----------------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:58194-044-50 | 50 in 1 JAR | 07/17/2016 | |
| 1 | NDC:58194-044-01 | 2 mL in 1 PATCH; Type 0: Not a Combination Product | | |
| | | | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part333D | 07/17/2016 | | |
| | | | | |

Labeler - Shanghai Weierya Daily Chemicals Factory (420359333)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Shanghai Weierya Daily Chemicals Factory | | 420359333 | manufacture(58194-044) | |

Revised: 7/2016 Shanghai Weierya Daily Chemicals Factory