

OILY SK BALANCING I - salicylic acid cream
LABORATORIOS DE COSMETICA SCIENTIFI

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.

Drug Facts

Active Ingredient

Salicylic Acid 1%

Purpose: Acne Treatment

Keep out of reach of children.

Uses: Daily treatment cream for acne-prone skin.

Warnings:

- For external use only.
- Avoid contact with eyes and mucous membranes.
- Discontinue use if signs of rash or irritation appear.

Directions: Apply a dime size amount to cleansed skin with a light massage. Use morning and night.

Other Ingredients: WATER, HYDROGENATED POLYDECENE, ALCOHOL DENAT., BUTYLENE GLYCOL, GLYCERYL STEARATE, PEG-100 STEARATE, DIMETHICONE, CETYL ALCOHOL, GLYCERIN, MAGNESIUM ALUMINUM SULFATE, ZINC PCA, CAPRYLOYL GLYCINE, METHYL METHACRYLATE CROSSPOLYMER, MALIC ACID, SODIUM SALICYLATE, BISABOLOL, XANTHAN GUM, ENANTIA CHLORANTHA BARK EXTRACT, PLANTAGO LANCEOLATA LEAF EXTRACT, HYPERICUM PERFORATUM EXTRACT, OLEANOLIC ACID, HYDROLYZED SWEET ALMOND PROTEIN, CITRUS MEDICA LIMONUM (LEMON) PEEL OIL, MENTHA PIPERITA (PEPPERMINT) OIL, BERBERIS AQUIFOLIUM EXTRACT, POLYSORBATE 80, PHENOXYETHANOL, METHYLPARABEN, BUTYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, ISOBUTYLPARABEN, SODIUM HYDROXIDE.

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DERMATOLOGICALLY TESTED

Laboratorios ATACHE S.A. ATACHE® USA INC.
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SPAIN - MADE IN EU ATLANTA, GA - 30305



AG PHARMA
www.atache.com
Ref. 040888

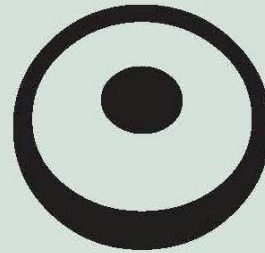


ATACHE
SCIENTIFIC COSMETIC

OILY SK

BALANCING
CREAM I

CREMA PURIFICANTE
PURIFYING CREAM
CRÈME PURIFIANTE
CREMA PURIFICANTE



50 ml e 1.69 FL OZ



Utilizzare prefer. antes de final de : / Best before:

- pantone METALLIC 8283 cv
- pantone 566 c
- TRAMA 40 % NEGRO = STAMPING PLATA MATE
NO IMPRIMIR ESTA TINTA
- BRAILLE NO IMPRIMIR ESTA TINTA

OILY SK BALANCING I

salicylic acid cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75870-009 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | .5 mL in 50 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SULFURIC ACID (UNII: O40UQP6WCF) | |
| ZINC PIDOLATE (UNII: C32PQ86DH4) | |
| MAHONIA AQUIFOLIUM FRUITING TOP (UNII: P119855ERN) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| MALIC ACID (UNII: 817L1N4CKP) | |
| SODIUM SALICYLATE (UNII: WIQ1H85SYP) | |
| LEVOMENOL (UNII: 24WE03BX2T) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| ANNICKIA CHLORANTHA BARK (UNII: H70115MP4A) | |
| PLANTAGO LANCEOLATA LEAF (UNII: 2YWL9J7EE8) | |
| HYPERICUM PERFORATUM LEAF (UNII: DOC7OB843Y) | |
| OLEANOLIC ACID (UNII: 6SMK8R7TGJ) | |
| ALMOND (UNII: 3Z252A2K9G) | |
| LEMON OIL (UNII: I9GRO824LL) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| MAHONIA AQUIFOLIUM FRUITING TOP (UNII: P119855ERN) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| BUTYL PARABEN (UNII: 3QPIU3FV8) | |
| ETHYL PARABEN (UNII: 14255EXE39) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| ISOBUTYL PARABEN (UNII: 0QQJ25X58G) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|-----------------|--|--|
| 1 | NDC:75870-009-02 | 1 in 1 CARTON | | |
| 1 | NDC:75870-009-01 | 50 mL in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D | 07/15/2007 | |

Labeler - LABORATORIOS DE COSMETICA SCIENTIFI(467582193)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|---------------------|
| LABORATORIOS DE COSMETICA SCIENTIFICA ATACHE | | 467582193 | manufacture |

Revised: 6/2011

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