

SKIN RELIEF CREAM- hydrocortisone lotion Spa de Soleil

Skin Relief Cream

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Inflammatory

Warnings

- For external use only.
- Avoid contact with the eyes
- If condition worsens or symptoms persist for more than seven days or clear up and occur again within a few days, stop use of this product and do not begin use of any hydrocortisone product until you have consulted a physician.
- Do not use for the treatment of diaper rash. Consult a physician.
- Keep out of reach of children.

Directions

Directions

- Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer one to three times daily

Directions(Continued)

- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • If bothersome dryness or peeling occurs, reduce application to once a day or every other day

Uses:

Protects skin from irritation and itching, promoting faster healing and renewal.

Inactive Ingredients:

Water, Caprylic/Capric Triglyceride, Glyceryl Stearate SE, Glycerin, Dimethicone, Propylene Glycol, Cetyl Alcohol, Sorbitol, Carthamus Tinctorius (Safflower) Seed Oil, **Squalane, Carbomer, Lactic Acid, Peg-4, Morus Alba Root Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Kojic Acid, Butylene Glycol, Arctostaphylos Uva-Ursi Leaf Extract, Sodium Hydroxide, Ruscus Aculeatus Root Extract, Ginkgo Biloba Leaf Extract,

Diospyros Kaki Fruit Extract, Betula Alba Bark Extract, DMAE, Thioctic Acid, Ubiquinone, *CO Glycerin, Citric Acid, Malic Acid, Gluconic Acid, Ascorbic Acid (Vitamin C), Malus Domestica Fruit Cell Culture Extract, Glycolic Acid, Salicylic Acid, Tartaric Acid, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, *CO Citrus Limon (Lemon) Peel Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Camellia Sinensis Leaf Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spirulina Platensis Extract, Xanthan Gum, Lecithin, Tocopheryl Acetate (Vitamin E), Retinyl Palmitate (Vitamin A), Benzyl Alcohol, Dehydroacetic Acid

Warning

Keep out of reach of children.

<p>SKIN RELIEF CREAM ER TREATMENT</p> <p>.....</p> <p>     </p> <p>VEGAN DAIRY-FREE GLUTEN-FREE NON-GMO</p> <p>.....</p> <p>1 fl. oz 30 mL</p>	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Hydrocortisone 1.0%</td> <td>Anti-inflammatory</td> </tr> <tr> <td colspan="2">Uses Temporarily protects skin from irritation and itching.</td> </tr> <tr> <td colspan="2">Warnings For external use only. Avoid contact with eyes. Do not use more than directed unless told to do so by a doctor Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">When using this product</td> </tr> <tr> <td colspan="2">• Do not get into eyes • Skin irritation and dryness is more likely to occur if you use another topical acne medication while using this product. If irritation occurs, use only one topical acne medication at a time.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2">• Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer one to three times daily</td> </tr> <tr> <td colspan="2">• Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • If bothersome dryness or peeling occurs, reduce application to once a day or every other day</td> </tr> <tr> <td colspan="2">Inactive Ingredients: Aqua, Caprylic/Capric Triglyceride, Glycerin, Cetyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Dimethicone, Sorbitol, Carthamus Tinctorius (Safflower) Seed Oil, Allantoin, Cyclopentasiloxane, Carbomer, **Squalane, Disodium EDTA, Sodium Hydroxide, *CO Glycerin, Malus Domestica Fruit Cell Culture Extract, *CO Aesculus Hippocastanum (Horse Chestnut) Seed Extract, *CO Prunus Armeniaca (Apricot) Fruit Extract, *CO Rosa Centifolia Flower Extract, *CO Rosmarinus Officinalis (Rosemary) Leaf Extract, Xanthan Gum, Lecithin, Ascorbic Acid (Vitamin C), Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Phenoxyethanol, Ethylhexylglycerin, Fragrance. *CO Certified Organic **From Sugarcane</td> </tr> <tr> <td colspan="2">Manufactured for:</td> </tr> <tr> <td colspan="2" style="text-align: right;"> ER1604-PL   MADE IN USA </td> </tr> </table>	Drug Facts		Active Ingredient	Purpose	Hydrocortisone 1.0%	Anti-inflammatory	Uses Temporarily protects skin from irritation and itching.		Warnings For external use only. Avoid contact with eyes. Do not use more than directed unless told to do so by a doctor Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		When using this product		• Do not get into eyes • Skin irritation and dryness is more likely to occur if you use another topical acne medication while using this product. If irritation occurs, use only one topical acne medication at a time.		Directions		• Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer one to three times daily		• Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • If bothersome dryness or peeling occurs, reduce application to once a day or every other day		Inactive Ingredients: Aqua, Caprylic/Capric Triglyceride, Glycerin, Cetyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Dimethicone, Sorbitol, Carthamus Tinctorius (Safflower) Seed Oil, Allantoin, Cyclopentasiloxane, Carbomer, **Squalane, Disodium EDTA, Sodium Hydroxide, *CO Glycerin, Malus Domestica Fruit Cell Culture Extract, *CO Aesculus Hippocastanum (Horse Chestnut) Seed Extract, *CO Prunus Armeniaca (Apricot) Fruit Extract, *CO Rosa Centifolia Flower Extract, *CO Rosmarinus Officinalis (Rosemary) Leaf Extract, Xanthan Gum, Lecithin, Ascorbic Acid (Vitamin C), Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Phenoxyethanol, Ethylhexylglycerin, Fragrance. *CO Certified Organic **From Sugarcane		Manufactured for:		ER1604-PL   MADE IN USA	
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SKIN RELIEF CREAM

hydrocortisone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-2266
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.45 mg in 45 mL
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Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-2266-1	30 mL in 1 TUBE; Type 0: Not a Combination Product	11/19/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	11/19/2023	

Labeler - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-2266)

Revised: 1/2026

Spa de Soleil