

DRY IT OUT ACNE SPOT TREATMENT- salicylic acid gel
Pacifica Beauty, LLC

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.

Dry It Out Acne Spot Treatment

Active ingredient Purpose

Salicylic Acid 2.0% Acne Medication

Use

For the treatment of acne.

Warnings

For external use only. Flammable: Keep away from fire or flame. When using this product: skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

When using this product: skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Keep out of reach of children.

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

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. Sensitivity test for a new user. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

Inactive ingredients:

Aqua, Alcohol Denat., Glycerin, Hamamelis Virginiana (Witch Hazel) Extract, Aloe Barbadensis Leaf Juice*, Hydroxyethylcellulose, Niacinamide, Cucumis Sativus

(Cucumber) Fruit Extract*, Spiraea Ulmaria (Meadowsweet) Extract, Salvia Officinalis (Sage) Oil, Mentha Piperita (Peppermint) Oil, Lens Esculenta (Lentil) Fruit Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract*, Chamomilla Recutita (Matricaria) Flower Extract*, Camellia Sinensis (White Tea) Leaf Extract*, Arnica Montana Flower Extract*, Dipotassium Glycyrrhizate, Parfum**. *certified organic **our scent blend with natural and/or essential oils

Questions or comments?

Call toll free 1-888-322-2466
 Pacifica Beauty LLC Portland, Oregon

Dry It Out Acne Spot Treatment Label

  <p>Witch hazel and maximum strength salicylic acid come together in this effective spot treatment designed to dry out blemishes on the spot. Additional ingredients include sage, cucumber, mint and niacinamide.</p> <p>Every true beauty knows it's what's on the inside that matters. Formulated without parabens, phthalates, SLS or mineral oil.</p> <p>#5 BOTTLE & CAP</p> <p>Made in USA with global ingredients. Pacifica Beauty LLC Portland, Oregon www.pacificabeauty.com</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Salicylic Acid 2.0%</td> <td>Acne Medication</td> </tr> </tbody> </table> <p>Use For the treatment of acne.</p> <p>Warnings</p> <p>For external use only. Flammable: Keep away from fire or flame. When using this product: •skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> •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. •sensitivity test for a new user. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above. <p>Inactive ingredients: Aqua, Alcohol Denat., Glycerin, Hamamelis Virginiana (Witch Hazel) Extract, Aloe Barbadensis Leaf Juice*, Hydroxyethylcellulose, Niacinamide, Cucumis Sativus (Cucumber) Fruit Extract*, Spiraea Ulmaria (Meadowsweet) Extract, Salvia Officinalis (Sage) Oil, Mentha Piperita (Peppermint) Oil, Lens Esculenta (Lentil) Fruit Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract*, Chamomilla Recutita (Matricaria) Flower Extract*, Camellia Sinensis (White Tea) Leaf Extract*, Arnica Montana Flower Extract*, Dipotassium Glycyrrhizate, Parfum*. *certified organic **our scent blend with natural and/or essential oils</p> <p>Questions or comments? Call toll free 1-888-322-2466 Pacifica Beauty LLC Portland, Oregon</p>	Active ingredient	Purpose	Salicylic Acid 2.0%	Acne Medication	<p>PACIFICA</p> <p>DRY IT OUT</p> <p>ACNE GEL SPOT TREATMENT maximum strength 2% salicylic acid acne medication + niacinamide</p> <p>dermatologist tested allergy tested safe for sensitive skin</p>  <p>100% VEGAN CRUELTY-FREE</p> <p>29 mL • 1 fl oz</p>	 <p>PACIFICA</p> <p>100% VEGAN • CRUELTY-FREE</p> <p>DRY IT OUT</p> <p>ACNE GEL SPOT TREATMENT maximum strength 2% salicylic acid acne medication + niacinamide</p> <p>29 mL • 1 fl oz</p>
Active ingredient	Purpose						
Salicylic Acid 2.0%	Acne Medication						

DRY IT OUT ACNE SPOT TREATMENT			
salicylic acid gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61197-122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
NIACINAMIDE (UNII: 25X51I8RD4)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALCOHOL (UNII: 3K9958V90M)	
HAMAMELIS VIRGINIANA WHOLE (UNII: V663Q8TEFU)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
CUCUMBER FRUIT OIL (UNII: R81Y52NPCT)	
SAGE OIL (UNII: U27K0H1H2O)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
WATER (UNII: 059QF0KO0R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61197-122-00	29 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	02/09/2023	

Labeler - Pacifica Beauty, LLC (868275517)**Establishment**

Name	Address	ID/FEI	Business Operations
Sun Deep Inc.		189788201	manufacture(61197-122)