# RAF FIVE - SPOT ON SALICYLIC ACID ROLL-ON ACNE TREATMENT- salicylic acid cream Cosmetic Solutions 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.

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## RAF™ Five - Spot On Salicylic Acid Roll-On Acne Treatment Drug Facts

#### **Active ingredient**

Salicylic acid 2.0%

#### **Purpose**

Acne treatment

#### Uses

for the management of acne.

#### **Warnings**

#### For external use only

#### When using this product

- Skin irritation and dryness are 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.
- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

#### Stop use and ask a doctor.

• If irritation becomes severe.

**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 this product.
- Roll on to 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**

Water (Aqua), Pentylene Glycol, Propanediol, PPG -12 /SMDI Copolymer, Niacinamide, Cetearyl Olivate, Ethoxydiglycol, Sorbitan Olivate, Cetearyl Alcohol Cannabidiol, Dipotassium Glycyrrhizate, Ergothioneine, Artemisia Vulgaris Oil Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Limon (Lemon) Peel Oil, Eucalyptus Globulus Leaf Oil, Juniperus Virginiana Oil, Mentha Citrata Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Vitis Vinifera (Grape) Seed Oil, Amylopectin Dextrin, Polydextrose, Hydroxyethylcellulose, Glyceryl Caprylate, Sclerotium Gum, Caprylhydroxamic Acid, Caprylyl Glycol.

Distributed by ILERA DERM LLC, a subsidiary of Zelira Therapeutics LTD. 5110 Campus Drive Plymouth Meeting, PA 19462

#### PRINCIPAL DISPLAY PANEL - 15 g Bottle Carton

RAF™ FIVE

**SPOT ON** 

SALICYLIC ACID ROLL-ON ACNE TREATMENT with CBD

Net Wt. 0.5oz. / 15g

#### Drug Facts (continued)

Inactive Ingredients

Water (Aqua), Pentylene Glycol, Propanediol, PPG -12 /SMDI Copolymer, Niacinamide, Cetearyl Olivate, Ethoxydiglycol, Sorbitan Olivate, Cetearyl Alcohol Cannabidiol, Dipotassium Glycyrrhizate, Ergothioneine, Artemisia Vulgaris Oil Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Limon (Lemon) Peel Oil, Eucalyptus Globulus Leaf Oil, Juniperus Virginiana Oil, Mentha Citrata Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Vitis Vinifera (Grape) Seed Oil, Amylopectin Dextrin, Polydextrose, Hydroxyethylcellulose, Glyceryl Caprylate, Sclerotium Gum, Caprylhydroxamic Acid, Caprylyl Glycol.

SPOT ON for pimple repair. Have a spot, see a spot, roll a little or roll a lot to knock-out pimples.

Developed with the proprietary Zylorma™ complex technology which features soothing hemp-derived CBD isolate and other botanicals to balance and moisturize your skin, and Salicylic acid to combat acne, help clear skin and prevent new blemishes from forming.





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a subsidiary of
Zelira Therapeutics LTD.
5110 Campus Drive
Plymouth Meeting,
PA 19462

www.raffiveskincare.com

#### **Drug Facts**

#### Active ingredient

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#### Purpose

Acne treatment

#### Uses

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#### Warnings

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- Avoid contact with eyes.
   If contact occurs, rinse eyes thoroughly with water.
   Stop use and ask a doctor.
- If irritation becomes severe.

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

#### Directions

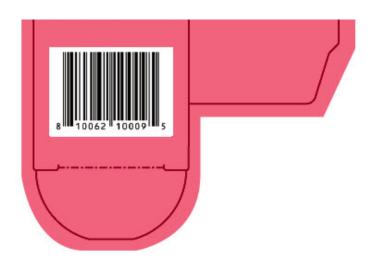
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SPOT ON

SALICYLIC ACID ROLL-ON ACNE TREATMENT with CBD

Net Wt. 0.5oz. / 15g





#### **RAF FIVE - SPOT ON SALICYLIC ACID ROLL-ON ACNE TREATMENT**

salicylic acid cream

**Product Information** 

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66163-4455

**Route of Administration** TOPICAL

**Active Ingredient/Active Moiety** 

Ingredient Name
Basis of Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)
SALICYLIC ACID
2 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Pentylene Glycol (UNII: 50C1307PZG)			
Propanediol (UNII: 5965N8W85T)			
PPG-12/SMDI Copolymer (UNII: 1BK9DDD24E)			
Niacinamide (UNII: 25X51I8RD4)			
Cetearyl Olivate (UNII: 58B69Q84JO)			
Diethylene Glycol Monoethyl Ether (UNII: A1A1I8X02B)			
Sorbitan Olivate (UNII: MDL271E3GR)			
Cetostearyl Alcohol (UNII: 2DMT128M1S)			
Cannabidiol (UNII: 19GBJ60SN5)			
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)			
Ergothioneine (UNII: BDZ3DQM98W)			
Artemisia Vulgaris Top Oil (UNII: 72Q967Y48V)			
Bergamot Oil (UNII: 39W1PKE3JI)			
Lemon Oil, Cold Pressed (UNII: 19GRO824LL)			
Eucalyptus Oil (UNII: 2R04ONI662)			
Juniperus Virginiana Oil (UNII: PAD4FN7P2G)			
Spearmint Oil (UNII: C3M81465G5)			
Grape Seed Oil (UNII: 930MLC8XGG)			

Polydextrose (UNII: VH2XOU12IE)	
Hydroxyethyl Cellulose, Unspecified (UNII: T4V6TWG28D)	
Glyceryl Monocaprylate (UNII: TM2TZD4G4A)	
Betasizofiran (UNII: 2X51AD1X3T)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Caprylyl Glycol (UNII: 00YIU5438U)	

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:66163- 4455-1	15 g in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	03/01/2021	

### Labeler - Cosmetic Solutions LLC (807907928)

Revised: 8/2021 Cosmetic Solutions LLC