

**MONAT ACNE TREATMENT- benzoyl peroxide cream**  
**Monat Global Corp**

*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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Benzoyl Peroxide 5%

Acne Treatment

For the treatment of acne.

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

Clean 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. If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

**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.

Water, Isostearyl Alcohol, Glycerin, Pentylene Glycol, Silica, Hamamelis Virginiana (Witch Hazel) Water, Epilobium Angustifolium Flower/Leaf/Stem Extract, Phragmites Communis Extract, Poria Cocos Extract, Niacinamide, Tocopheryl Acetate, Carbomer, Potassium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA.

**For external use only. Do not use** if you have very sensitive skin or are sensitive to benzoyl peroxide. **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 treatment at a time, avoid unnecessary sun exposure and use sunscreen, avoid contact with eyes, lips, and mouth, avoid contact with hair and dyed fabrics, which may be bleached by this product, skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration. **Stop use and consult with a doctor** if irritation becomes severe.

**Package Label**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Benzoyl Peroxide 5.00%	Acne Treatment
<b>Uses</b>	
• For the treatment of acne	
<b>Warnings</b>	
<b>For external use only.</b>	
<b>Do not use if you</b> • have very sensitive skin • are sensitive to benzoyl peroxide.	
<b>When using this product:</b> • 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 treatment at a time. • avoid unnecessary sun exposure and use sunscreen • avoid contact with eyes, lips, and mouth • avoid contact with hair and dyed fabrics, which may be bleached by this product • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.	
<b>Stop use and consult with a doctor if</b>	
• irritation becomes severe.	
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a poison control center right away.	
<b>Directions</b>	
• Clean 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 • if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.	
<b>Sensitivity Test for a New User.</b> Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.	
<b>Inactive Ingredients</b>	
Water/Aqua/Eau, Isostearyl Alcohol, Glycerin, Pentylene Glycol, Silica, Hamamelis Virginiana (Witch Hazel) Water, Epilobium Angustifolium Flower/Leaf/Stem Extract, Phragmites Communis Extract, Poria Cocos Extract, Niacinamide, Tocopheryl Acetate, Carbomer, Potassium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA.	
<b>Other information</b> Store at 20-25°C (68-77°F)	
<b>Questions or comments?</b>	
Toll-free number: 1-800-878-1978	

PRODUCT OF U.S.A.  
 Manufactured for: MONAT Global Corp.,  
 Doral, FL 33172, USA

www.monatglobal.com

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MONAT

BE CLARIFIED™

Spot Treatment  
 Acne Treatment  
 Cream

15 ml e 0.5 fl.oz.

NORMAL / COMBINATION / OILY

We Are  
 Modern Nature™

A maximum-strength,  
 fast-acting spot  
 treatment that absorbs  
 quickly into the skin for  
 fast, visible results.  
 Targets and clears  
 existing blemishes  
 while preventing new  
 breakouts.

## MONAT ACNE TREATMENT

benzoyl peroxide cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78518-295

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>HAMAMELIS VIRGINIANA TOP WATER</b> (UNII: NT00Y05A2V)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP</b> (UNII: 08H094218D)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FU LING</b> (UNII: XH37TWY5O4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>PHRAGMITES AUSTRALIS STEM</b> (UNII: 3AW23L82V4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78518-295-01	15 mL in 1 TUBE; Type 0: Not a Combination Product	03/21/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	03/21/2023	

**Labeler** - Monat Global Corp (027036949)

**Registrant** - Derma Care Research Labs, LLC (116817470)

### Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 3/2023

Monat Global Corp