

**ACNE SPOT 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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**MONAT Be Clarified Spot Treatment**

***Active Ingredient***

Benzoyl Peroxide 5.00%

***Purpose***

Acne Treatment

***Uses***

- For the treatment of acne

**For external use only**

**Do not use if**

**Do not use if you**

- have very sensitive skin
- are sensitive to benzoyl peroxide

**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 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**

**Stop use and consult with a doctor if**

- irritation becomes severe.

**Keep out of reach of children**

**Keep out of reach of children.** If product is swallowed, get medical help or contact a poison control center right away.

**Directions**

***Directions***

- 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 see 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.

### ***Inactive Ingredients***

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.

### **Questions or Comments**

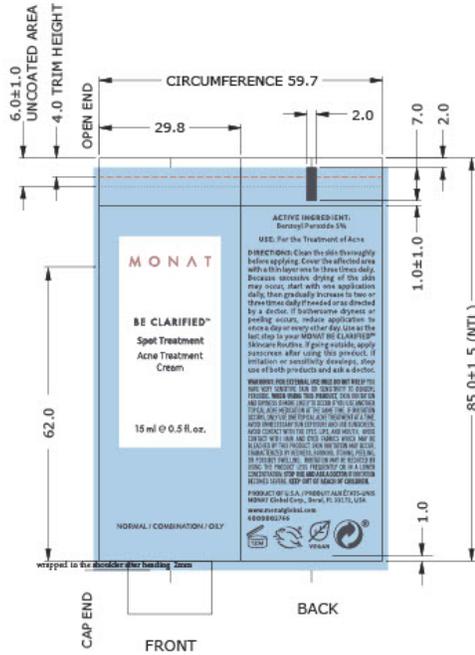
#### ***Questions or comments?***

Toll-free number 1-800-878-1978

### **PRIMARY PACKAGE**

Printed Date:

DO NOT SCALE DRAWING



ART HISTORY AND NOTES	
CREATED:	04/12/2022
LAST REVISED BY:	04/12/2022 NT: Created File
	05/23/2022 NT: Copy edit
	05/25/2022 NT: Warning

PO#: P2759  
 Name: \_\_\_\_\_  
 Code: 6000002766  
 Spec: D19x85mm

MONAT GLOBAL CORP., DIST	
ITEM NUMBER:	BE CLARIFIED™ Spot Treatment 15 ml (0.5 oz)
6000002766	
COLOR REQUIREMENTS:	
<span style="color: blue;">■</span> PANTONE 545 U	<span style="color: blue;">■</span> SOFT TOUCH
<span style="color: black;">■</span> PANTONE Black 6 U	
<span style="color: brown;">■</span> CUSTOM ROSE GOLD HS	
<span style="color: white;">■</span> WHITE	

Tube Color: White

Print Process: 2C Offset Printing  
■ PANTONE 545 U  
■ PANTONE Black U (eyemark)

Print Process: 1C Silk Screen Printing  
■ PANTONE Black 6 U

Print Process: 1C Hot stamp Printing  
■ CUSTOM ROSE GOLD HS

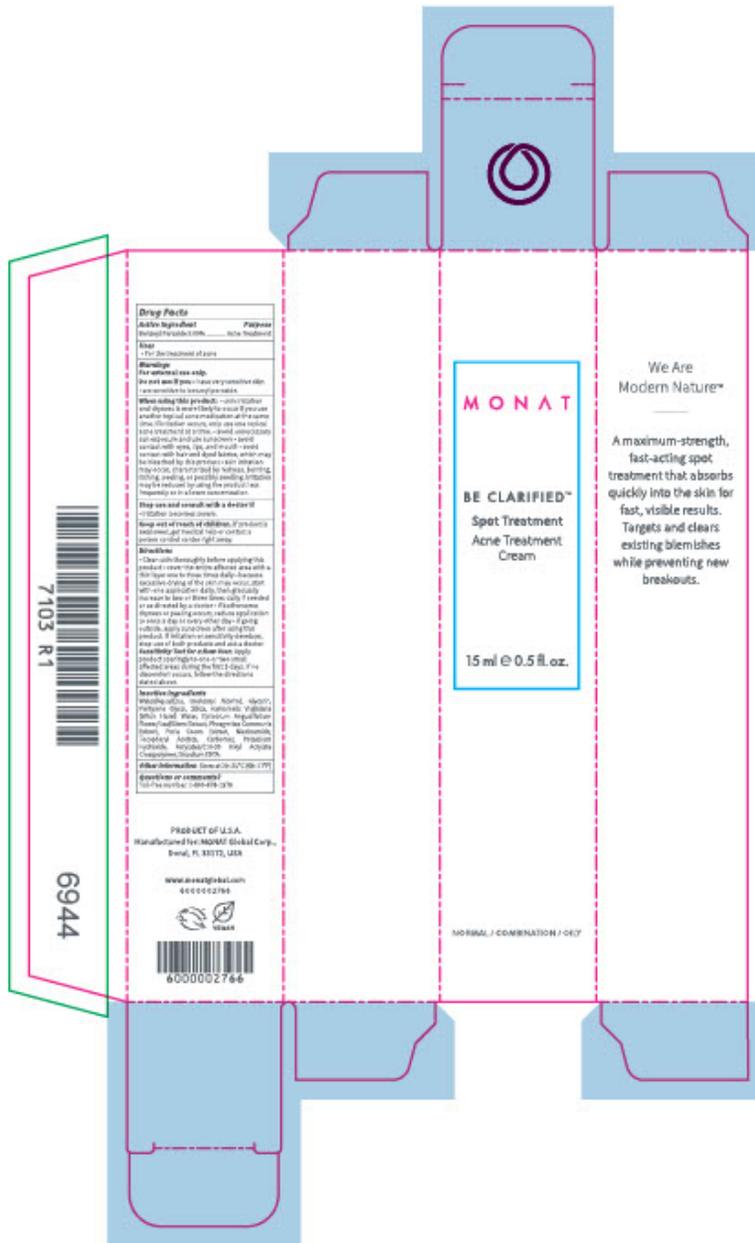
Coating: Soft Touch  
■ Soft Touch  
 Overall Varnish

	1	2	3	4	5	6
COLOR						
PMS						

*Handwritten signature* 06/07/2022

 15 Vreeland Rd., Ste. #4 Florham Park, NJ 07932	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS TOLERANCES: PRECISION: LINEAR: ±0.15 X = ±0.1 ANGULAR: ±0°30' XX = ±0.05	Est. Volume (cu.cm): 19mm Cap and Tube Drawn By: Part Name: Material: DECO 19X85	Supplier: WWP Suzhou
	Date: 05/27/22 SHT: A-4 Dwg. No.: 398 - 19x85	Rev.: Project No.: 398 Status: Production	Part Code:

**OUTER PACKAGE**



Customer		Process Colors		SPECTRUM PACKAGING CORPORATION		3840 Princeton Oaks St. • Orlando, FL 32808	
Monat Global				This Proof is Color Accurate For: <input checked="" type="checkbox"/> Color Breaks <input type="checkbox"/> Process Color <input type="checkbox"/> Revised proof with indicated changes required. *Any revision will require a new signed proof.		Item Index / SKU	
Project Name / Description		Spot Colors		APPROVED FOR COPY		7103 R1	
200001432 Be Clarified Acne Spot Treatment 15ml Carton		Black 6 U    542 U    UV HS Extender Coatings Deboss    Emboss    Rose Gold Foil Stamp, Kurz Luxor		Jesus Bonaguro Signature		DIGITALLY APPROVED FOR COPY	
Dimensions				01/17/23		Date	
0.875 x 0.875 x 4.8125				Endicott		Operator	
Operator		Date		Endicott		01-12-23	
Endicott		01-12-23		Endicott		01-12-23	

# ACNE SPOT TREATMENT

benzoyl peroxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78518-013
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)	
<b>DISODIUM EDTA-COPPER</b> (UNII: 6V475AX06U)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)	
<b>EPILOBIUM ANGUSTIFOLIUM LEAF</b> (UNII: 7NV86426N2)	
<b>HAMAMELIS VIRGINIANA LEAF WATER</b> (UNII: 8FP93ED6H2)	
<b>FU LING</b> (UNII: XH37TWY5O4)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78518-013-01	1 in 1 CARTON	04/04/2023	
1		15 mg in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	04/04/2023	

**Labeler** - MONAT GLOBAL CORP (027036949)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Dermacare MFG		116817470	manufacture(78518-013)

Revised: 4/2023

MONAT GLOBAL CORP