BENZOAZELINE 5- benzoyl peroxide cream Noon Aesthetics M.R. Ltd

BenzoAzeline 5

Drug Facts

Active Ingredient

Benzoyl Peroxide 5%

Purpose

Acne Medication

Uses

• For the treatment of acne.

Warnings

For external use only.

Do not use if you

- have very sensitive skin.
- 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 medication at a time.
- avoid unnecessary sun exposure and use a sunscreen.
- avoid contact with the 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 ask a doctor if

• irritation becomes severe.

Keep out of reach of children.

• If swallowed, get help or contact a Poison Control Center right away.

Directions

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 below.

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

Other Information

Protect this product form excessive heat and direct sun.

Inactive Ingredients

Water (Aqua), Azelaic Acid, Strontium Chloride Hexahydrate, Dimethyl Sulfone, Potassium Azeloyl Diglycinate, Propanediol, Propylene Glycol, Ethanol, Oleic Acid, Glyceryl Stearate, PEG-100 Stearate, Benzyl Benzoate, Arachidyl Alcohol, Cetearyl Glucoside, Cetearyl Alcohol, Xylitol, Anhydroxylitol, Phenoxyethanol, Behenyl Alcohol, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, Arachidyl Glucoside, Xylitylglucoside, Disodium EDTA, Caprylyl Glycol, Glucose.

Developed + Dist by noon AESTHETICS

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

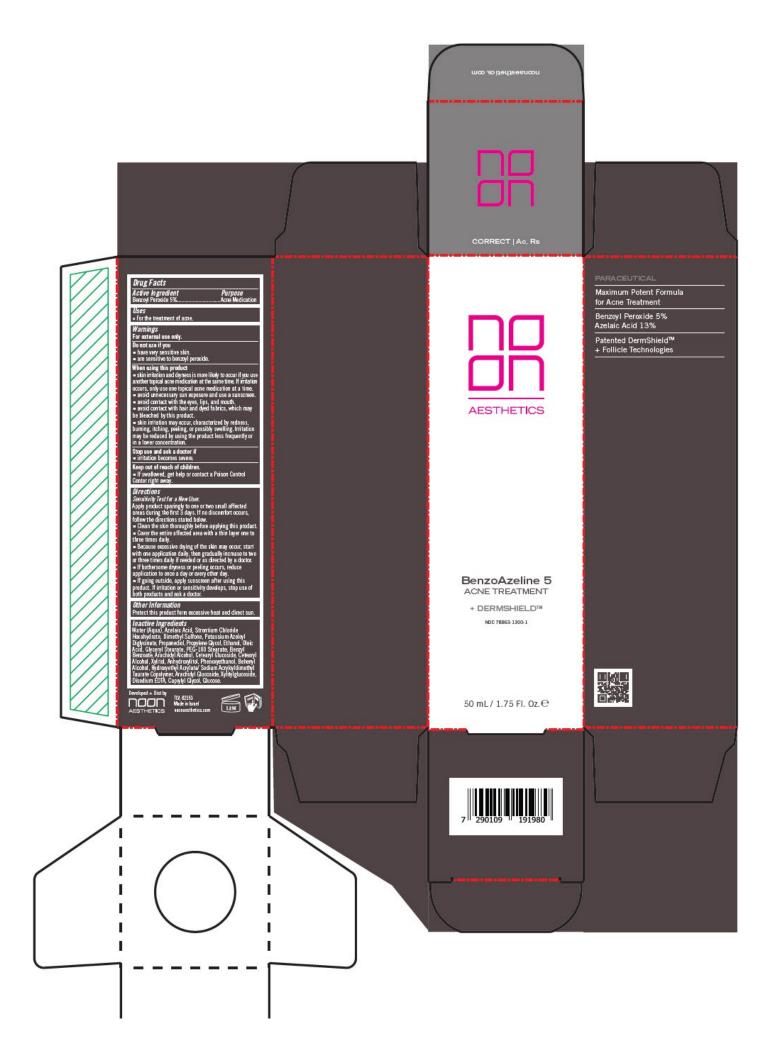
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BenzoAzeline 5 ACNE TREATMENT

+ DERMSHIELD™

NDC 78863-1300-1

50 mL / 1.75 Fl. Oz. e



BENZOAZELINE 5

benzoyl peroxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78863-1300

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII: W9WZN9A0GM)	BENZOYL PEROXIDE	500 mg in 1 mL		

Inactive Ingredients	
-	Ctwo marth
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AZELAIC ACID (UNII: F2VW3D43YT)	
POTASSIUM AZELOYL DIGLYCINATE (UNII: N02RVN6NYP)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
STRONTIUM CHLORIDE HEXAHYDRATE (UNII: 009USB7Z44)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PROPANEDIOL (UNII: 5965N8W85T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OLEIC ACID (UNII: 2UMI9U37CP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
BENZYL BENZOATE (UNII: N863NB338G)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
XYLITOL (UNII: VCQ006KQ1E)	
ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
DOCOSANOL (UNII: 9G10E216XY)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:78863- 1300-1	1 in 1 CARTON	03/01/2024		
1		50 mL in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:78863- 1300-2	1 in 1 CARTON	03/01/2024		
2		15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph drug	M006	03/01/2024		

Labeler - Noon Aesthetics M.R. Ltd (600185560)

Establishment				
Name	Address	ID/FEI	Business Operations	
Noon Aesthetics M.R. Ltd		600185560	MANUFACTURE(78863-1300)	

Revised: 2/2024 Noon Aesthetics M.R. Ltd