

ACNE DEFENSE DAILY TREATMENT SERUM MERLE NORMAN- benzoyl peroxide gel **Merle Norman Cosmetics**

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.

Acne Defense Daily Treatment Serum

Active (medicinal)	Purpose
Benzoyl Peroxide 2.5%	Acne Treatment

Uses

For the treatment of acne

Dries and helps clear up acne pimples and allows skin to heal
helps prevent new acne pimples from forming

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

Stop use and ask a doctor if

- irritation becomes severe

Warnings

For external use only

Do not use if

- 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 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

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 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

Inactive (Non-medicinal) Ingredients

Water, Glycerin, Isopropyl Myristate, Pentylene Glycol, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Disodium EDTA

Acne Defense Daily Treatment Serum

Gel

33g

Net Wt. 1.15 Oz

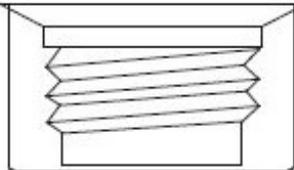
 MERLE NORMAN WWW.MERLENORMAN.COM							
<p>Drug Facts</p> <table border="1"><thead><tr><th>Active (medicinal) ingredient (w/w):</th><th>Purpose</th></tr></thead><tbody><tr><td>Benzoyl Peroxide 2.5%</td><td>Acne Treatment</td></tr></tbody></table> <p>Use • for the treatment of acne, • dries and helps clear up acne pimples and allows skin to heal. • helps prevent new acne pimples from forming.</p> <p>Warnings</p> <p>For external use only</p> <p>Do not use if you • have very sensitive skin. • are sensitive to benzoyl peroxide.</p> <p>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.</p> <p>Stop use and ask a doctor if • irritation becomes severe.</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 ▶	Active (medicinal) ingredient (w/w):	Purpose	Benzoyl Peroxide 2.5%	Acne Treatment	<p>Drug Facts (continued)</p> <p>daily if needed or 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.</p> <p>Inactive (Non-Medicinal) Ingredients: Water, Glycerin, Isopropyl Myristate, Pentylene Glycol, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Disodium EDTA.</p> <p>Questions & comments? 1-800-348-8889 8:00 a.m. - 5:00 p.m. PST</p>	<p>ACNE DEFENSE DAILY TREATMENT SERUM</p>	<p>A lightweight, comforting and hydrating serum designed to treat acne, help refine pores and reduce excess oil. Can be used alone or followed by moisturizer. Dermatologist tested.</p>
Active (medicinal) ingredient (w/w):	Purpose						
Benzoyl Peroxide 2.5%	Acne Treatment						
MERLE NORMAN ESTABLISHED IN LOS ANGELES SINCE 1931							
<p>GEL</p> <p>33 g e NET WT. 1.15 OZ.</p>		 MERLE NORMAN COSMETICS LOS ANGELES, CA 90045 MADE IN U.S. OF U.S. AND IMPORTED PARTS					
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**ACNE DEFENSE
DAILY TREATMENT SERUM**

MERLE NORMAN

GEL

33 g e NET WT. 1.15 OZ.



A lightweight, comforting and hydrating serum designed to treat acne, help refine pores and reduce excess oil. Can be used alone or followed by moisturizer. Dermatologist tested.

**Active (medicinal)
ingredient (w/w)**

Benzoyl Peroxide 2,5%treatment

Use • for the treatment of acne. • dries and helps clear up acne pimples and allow skin to heal. • helps prevent new acne pimples from forming.

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MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN U.S. OF U.S.
AND IMPORTED PARTS



ACNE DEFENSE DAILY TREATMENT SERUM MERLE NORMAN

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRVV)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-202-02	1 in 1 CARTON	07/14/2017	
1	NDC:57627-202-01	33 g 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	part333D	07/14/2017	

Labeler - Merle Norman Cosmetics (008479388)**Registrant** - Merle Norman Cosmetics (008479388)**Establishment**

Name	Address	ID/FEI	Business Operations
Merle Norman Cosmetics		008479388	manufacture(57627-202)

Revised: 1/2020

Merle Norman Cosmetics