BENZEFOAM ULTRA- benzoyl peroxide aerosol
Bausch Health US, 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.

Drug Facts

Active ingredient

Benzoyl Peroxide (9.8%)

Purpose

Acne Treatment

Use

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 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 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.
- do not puncture or incinerate container. Contents under pressure.
- do not expose to temperatures above 120°F (49°C).

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

- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily
- rinse off after 2 minutes
- 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
- to be used as a short contact application

Other Information

■ store at room temperature 15°-25°C (59°-77°F). Protect from freezing. Store upright.

Inactive Ingredients

BHT, C12-15 alkyl benzoate, cetearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, hydrofluorocarbon 134a, methylparaben, propylene glycol, propylparaben, purified water,

sodium citrate, steareth-10

Questions/comments?

Call: 1-800-321-4576

Package/Label Principal Display Panel - Carton

NDC: 0187-0194-10

BenzEFoam Ultra

benzoyl peroxide 9.8%

Acne Treatment
Short Contact Foam

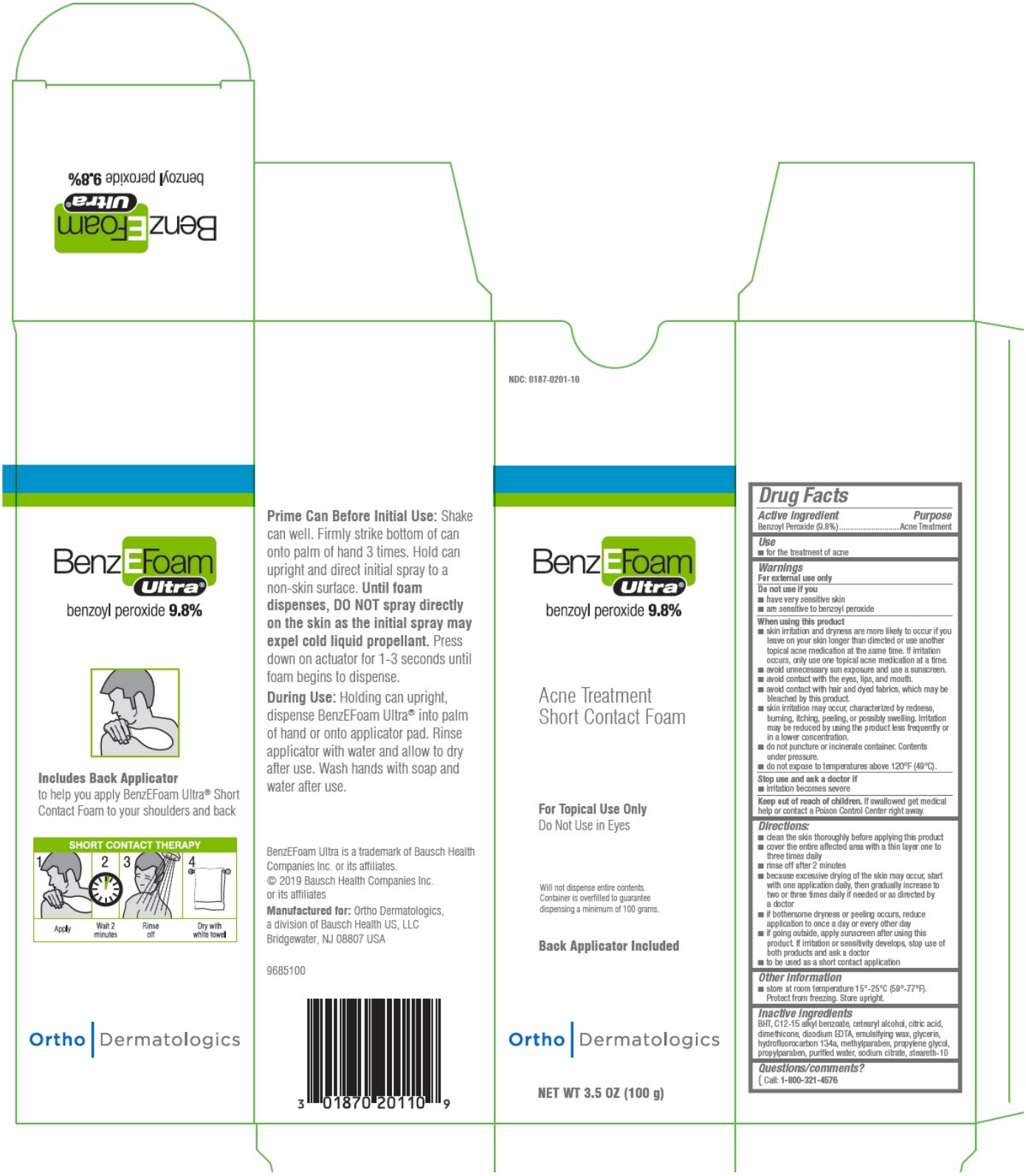
For Topical Use Only
Do Not Use in Eyes

Will not dispense entire contents.
Container is overfilled to guarantee
dispensing a minimum of 100 grams.

Back Applicator Included

Ortho Dermatologics

Net Wt 3.5 OZ (100 g)



BENZEFOAM ULTRA

benzoyl peroxide aerosol

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0187-0201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	9.8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
NORFLURANE (UNII: DH9E53K1Y8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
STEARETH-10 (UNII: FD0913P475)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0187-0201-10	1 in 1 CARTON	02/06/2020	
1		100 g in 1 CAN; 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	02/06/2020	

Labeler - Bausch Health US, LLC (831922468)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals		001207208	MANUFACTURE(0187-0201)

Revised: 2/2020 Bausch Health US, LLC