# AF FOAM CLEAR SKIN ACNE PORE CLEANSER - benzoyl peroxide aerosol, foam University Medical Pharmaceuticals 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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#### AF Foam CS Acne Pore Cleanser

**Active Ingredient**: Benzoyl Peroxide 2.5% w/v

**Purpose:** Acne Treatment

**Use** for the treatment of acne.

Warnings For external use only.

**Do not use:** If you are sensitive to Benzoyl Peroxide or have very sensitive skin. This product may cause irritation.

**Ask a doctor or pharmacist before use:** If you are using other topical acne drugs at the same time or right before use of this product. This may increase dryness, redness or irritation of the skin. If this occurs, only one medication should be used unless a doctor directs otherwise.

## When using this product:

- Avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth.
- Avoid unnecessary sun exposure and use a sunscreen.
- Avoid product with hair and dyed fabrics, including carpets and clothing which may be bleached by this product.

**Stop use and ask a doctor:** If excessive irritation occurs.

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

#### **Directions**

- Use AM and PM. Recommended: After AM use, follow with AcneFree All-Day Acne Control. After PM use, follow with 3-in-1 Acne Night Repair.
- Moisten skin.
- Shake well before each use.
- Hold Can upright and press down firmly on dispenser. Apply a small amount of foam (not more than a dollop the size of a gold ball) into hand.
- Using fingers, apply to face and gently massage to cleanse.
- Rinse thoroughly with warn water and pat dry.
- If bothersome peeling occurs, reduce application use.
- If going outside, use a sunscreen.

Inactive ingredients: Benzylkonium Chloride, Caprylic/Capric Triglyceride, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Decyl Glucoside, Disodium Laureth Sulfosuccinate, Ethylhexylglycerin, Glycerin, Glyceryl Sterate, Isobutane, Magnesium Aluminum Silicate, Methylisothiazolinone, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propane, Sea Whip Extract, Sodium Benzoate, Sodium Polyacrylate, Stearic Acid, Water, Xanthan Gum.

#### Other Information

- Store at 60°-85°F (15°-30°C).
- Pressurized container: protect from sunlight and do not expose to temperatures exceeding 120°F(49°C). Do not puncture or birn, even after use. Use only as directed.

#### AcneFree Clear Skin treatments

Oil-Free Acne Pore Cleanser Micro-Benzoyl Peroxide 2.5%

Rinse-Off Foam Medicine Stays in Pores Even After Rinsing

## **Drug Facts** (continued)

## Warnings

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## Drug Facts (continued)

### **Directions**

- Use AM and PM. Recommended: After AM use, follow with AcneFree® All-Day Acne Control. After PM use, follow with AcneFree 3-in-1 Acne Night Repair.
- Moisten skin.
- Shake well before each use.
- Hold can upright and press down firmly on dispenser. Apply a small amount of foam (not more than a dollop the size of a golf ball) into hand.
- Using fingers, apply to face and gently massage to cleanse.
- Rinse thoroughly with warm water and pat dry.
- If bothersome peeling occurs, reduce application use.
- If going outside, use a sunscreen.

#### Other information

- Store at 60°-85° F (15°-30° C).
- Pressurized container: protect from sunlight and do not expose to temperatures exceeding 120° F (49° C). Do not puncture or burn, even after use. Use only as directed.

Inactive Ingredients Benzalkonium Chloride, Caprylic/Capric Triglyceride, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Decyl Glucoside, Disodium Laureth Sulfosuccinate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Isobutane, Magnesium Aluminum Silicate, Methylisothiazolinone, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propane, Sea Whip Extract, Sodium Benzoate, Sodium Polyacrylate, Stearic Acid, Water, Xanthan Gum.

AFCF-0101

Questions or Comments? 1-800-535-0000 M-F 8 a.m.-5 p.m. (PST) acnefree.com





## AF FOAM CLEAR SKIN ACNE PORE CLEANSER

benzoyl peroxide aerosol, foam

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50544-301

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9 WZN9 A0 GM) (Benzoyl Peroxide - UNII:W9 WZN9 A0 GM)	Benzoyl Peroxide	2.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
DISO DIUM LAURETH SULFO SUCCINATE (UNII: D6 DH1DTN7E)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
glycerin (UNII: PDC6A3C0OX)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
MATRICARIA RECUTITA (UNII: G0 R4UBI2ZZ)	
propane (UNII: T75W9911L6)	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)	
PSEUDO PTERO GO RGIA ELISABETHAE (UNII: UDY3H1OUX5)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
isobutane (UNII: BXR49TP611)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)	

Package Description	Marketing Start Date	Marketing End Date
85 g in 1 CAN		
	8 1	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	11/0 1/20 11		

# Labeler - University Medical Pharmaceuticals Corp (809706252)

## **Registrant -** University Medical Pharmaceuticals Corp (809706252)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Universal Packaging Systems, INC		177711082	manufacture

Revised: 12/2011 University Medical Pharmaceuticals Corp