

OIL-FREE ACNE CLEANSER - benzoyl peroxide cream
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.

Oil-Free Acne 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 every morning and evening. Apply a dime-size amount to damp skin and gently massage, avoiding the eye area. Rinse well. If bothersome peeling occurs, reduce application use. May also be used on chest or back.

Inactive ingredients: Water, Disodium Laureth Sulfosuccinate, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, Glycerin, Cocamidopropyl Betaine, Bakuchiol, Panthenyl Triacetate, Bisabolol, Benzalkonium Chloride, Chamomilla Recuita (Matricaria) Flower Extract, Naringenin, Sea Whip Extract, Polyethylene, Xanthan Gum, Cetyl Alcohol, Magnesium Aluminum Silicate, Sodium Benzoate, Caprylic/Capric Triglyceride, Farnesol, Phenoxyethanol, Ethylhexylglycerin, Methylisothiazolinone.

AcneFree Clear Skin Treatments

Oil-Free Acne Cleanser
Gentle Exfoliating Microbeads

Advanced Micro-Benzoyl Peroxide

NEW
ADVANCED FORMULA
KILLS 99% OF ACNE BACTERIA



Oil-Free Acne Cleanser

Gentle Exfoliating Microbeads

ADVANCED MICRO-BENZOYL PEROXIDE



8 FL. OZ. (237 mL)

Drug Facts

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AFCS-0101-00



Questions or Comments?

1-800-535-0000 M-F 8 a.m.–5 p.m. (PST) acnefree.com

Dist. by: UNIVERSITY MEDICAL PHARMACEUTICALS CORP.

Irvine, CA 92618 Made in USA ©2011

C10444

OIL-FREE ACNE CLEANSER

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50544-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (benzoic acid - UNII:8SKN0B0MIM)	Benzoyl Peroxide	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

water (UNII: 059QF0KO0R)
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
STEARIC ACID (UNII: 4ELV7Z65AP)
glycerin (UNII: PDC6A3C0OX)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)
LEVOMENOL (UNII: 24WE03BX2T)
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)
PSEUDOPTEROGORGIA 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)
CETYL ESTERS WAX (UNII: D072FFP9GU)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50544-001-06	237 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	11/01/2011	

Labeler - University Medical Pharmaceuticals Corp (809706252)

Registrant - University Medical Pharmaceuticals Corp (809706252)

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