ACNE CLEANSER- benzoyl peroxide cream
Old East Main Co.

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.

Dollar General_Studio Selection 264.005/264AI rev 1 Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

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 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 bleaced by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling or possible 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 medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Directions

- wet face. Gently massage all over face for 20-30 seconds avoiding the eyes. Rinse thoroughly and pat dry.
- 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 daily 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
- *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 above.

Other information

- keep tightly closed
- store at room temperature (59^0-77^0)

Inactive ingredients

water, cetyl alcohol, petrolatum, acrylates/C10-30 alkyl acrylate crosspolymer, zinc lactate, steareth-2, glycerin, potassium cetyl phosphate, xanthan gum, benzyl alcohol, fragrance, disodium EDTA, laureth-4, BHT, sodium hydroxide, lactic acid, menthol

Adverse reaction

*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, distributor of Clean & Clear Continuous Control Acne Cleanser

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

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principal display panel

STUDIO

SELECTION

ACNE

CONTROL

CLEANSER

ACNE

MEDICATION

BENZOYL PEROXIDE 10%

Compare to Clean & Clear

Continuous Control Acne Cleanser

Provides daily control

- Cleanser for acne prone skin
- Helps fight blemishes

NET WT 5 OZ (141 g)

ACNE CLEANSER

benzoyl peroxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-264
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	104 mg in 10 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ZINC LACTATE (UNII: 2GXR25858Y)	
STEARETH-2 (UNII: V56DFE46J5)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
xanthan gum (UNII: TTV12P4NEE)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAURETH-4 (UNII: 6HQ855798J)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LACTIC ACID (UNII: 33X04XA5AT)	
MENTHOL (UNII: L7T10EIP3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-264-56	141 g in 1 TUBE; Type 0: Not a Combination Product	02/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/18/2014	

Labeler - Old East Main Co. (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-264)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-264)

Revised: 2/2022

Old East Main Co.