FACE VALUES ACNE MEDICATION- benzoyl peroxide gel
HARMON STORES, INC.

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.

FACE VALUES ACNE MEDICATION 10% BENZOYL PEROXIDE GEL

Active ingredient

Benzoyl Peroxide 10%

Purpose

Acne Medication

Uses

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

- avoid contact with the eyes, lips, and mouth
- avoid unnecessary sun exposure and use a sunscreen
- 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.
- 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.

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
- Becasue 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.

Inactive ingredients

carbomer, disodium EDTA, hydroxypropyl methylcellulose, laureth-4, sodium hydroxide, water

FACE VALUES ACNE MEDICATION 10% BENZOYL PEROXIDE GEL

1 OZ (28.3g)

NDC 63940-063-16

FACE VALUES ACNE MEDICATION 10% BENZOYL PEROXIDE GEL
BLISTER PACK

NDC 63940-063-17

J. Pope

9/11/2018

FACE VALUES ACNE MEDICATION

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63940-063
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
LAURETH-4 (UNII: 6HQ855798J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63940-063-17	1 in 1 CARTON	11/15/2010	
1	NDC:63940-063-16	28.3 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	11/15/2010	

Labeler - HARMON STORES, INC. (804085293)

Registrant - FRUIT OF THE EARTH, INC. (079559467)

Establishment

Name	Address	ID/FEI	Business Operations
FRUIT OF THE EARTH, INC.		008193513	manufacture(63940-063)

Revised: 3/2020 HARMON STORES, INC.