RUGBY BENZOYL PEROXIDE ACNE MEDICATION- benzoyl peroxide gel
NuCare Pharmaceuticals,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.

Rugby ® 10% Benzoyl Peroxide Gel

Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

Use

for the treatment of acne

Warnings

For external use only

Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide.

When using this product

n keep away from eyes, lips and mouth

- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with hair or dyed fabric, including carpet and clothing which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Mild irritation may be reduced by using the product less frequently or in a lower concentration. If irritation becomes severe, discontinue use; if irritation still continues, consult a doctor.
- using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with the eyes. If contact occurs, flush thoroughly with water.

Directions

Cleanse skin thoroughly before applying medication. Cover the entire affected area with a thin layer 1-3 times daily. If bothersome dryness or peeling occurs, reduce application to once a day.

Other information

Keep tightly closed. Avoid storing at extreme temperatures (below 40° F and above 100° F).

Inactive ingredients

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

Questions or comments?

1-800-645-2158

Distributed by:
Rugby Laboratories
31778 Enterprise Drive
Livonia, MI 48150

PRINCIPAL DISPLAY PANEL -

RUGBY BENZOYL PEROXIDE ACNE MEDICATION

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4393(NDC:0536-1056)

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 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAURETH-4 (UNII: 6HQ855798J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4393-1	42.5 mL in 1 BOX; Type 0: Not a Combination Product	04/13/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/20/2015	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4393)