PERRIGO BENZOYL PEROXIDE HYDROALCOHOLIC BASE- benzoyl peroxide gel
Rebel Distributors Corp

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

BENZOYL PEROXIDE ALCOHOL BASE GEL, 5%

Benzoyl Peroxide Gel 5% ***Hydroalcoholic Base Acne Gel***

Benzoyl Peroxide Gel 10% ***Hydroalcoholic Base Acne Gel***

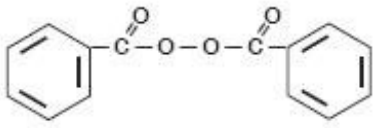
Rx Only

DESCRIPTION

Benzoyl Peroxide Gel 5% and 10% (Hydroalcoholic Base Acne Gels) are topical preparations containing benzoyl peroxide as the active ingredient.

Benzoyl Peroxide Gel 5% contains: 5% benzoyl peroxide in a hydroalcoholic gel base formulated with alcohol (12%, denatured with tert-butyl alcohol and denatonium benzoate), citric acid, disodium lauryl sulfosuccinate, hypromellose, laureth-12, magnesium aluminum silicate, and purified water. Benzoyl Peroxide Gel 10% contains: 10% benzoyl peroxide in a hydroalcoholic gel base formulated with alcohol (20%, denatured with tert-butyl alcohol and denatonium benzoate), citric acid, hypromellose, laureth-12, magnesium aluminum silicate, and purified water.

The structural formula of benzoyl peroxide is:



CLINICAL PHARMACOLOGY

The exact method of action of benzoyl peroxide in acne vulgaris is not known. Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes.* This action, combined with the mild keratolytic effect of benzoyl peroxide is believed to be responsible for its usefulness in acne. Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and excreted as benzoate in the urine.

INDICATIONS AND USAGE

Benzoyl Peroxide Gel 5% and 10% are indicated for use in the topical treatment of mild to moderate acne vulgaris. Benzoyl Peroxide Gel 5% and 10% may be used as an adjunct in acne treatment regimens including antibiotics, retinoic acid products, and sulfur/salicylic acid containing preparations.

CONTRAINDICATIONS

Benzoyl Peroxide Gel 5% and 10% should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the products.

PRECAUTIONS

General

For external use only. Avoid contact with eyes and mucous membranes. **AVOID CONTACT WITH HAIR, FABRICS OR CARPETING AS BENZOYL PEROXIDE WILL CAUSE BLEACHING.**

Carcinogenesis, Mutagenesis, Impairment of Fertility

Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice known to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with benzoyl peroxide. It is also not known whether benzoyl peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl peroxide should be used by a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children below the age of 12 have not been established.

ADVERSE REACTIONS

Contact sensitization reactions are associated with the use of topical benzoyl peroxide products and may be expected to occur in 10 to 25 of 1000 patients. The most frequent adverse reactions associated with benzoyl peroxide use are excessive erythema and peeling which may be expected to occur in 5 of 100 patients. Excessive erythema and peeling most frequently appear during the initial phase of drug use and may normally be controlled by reducing frequency of use.

DOSAGE AND ADMINISTRATION

It is recommended that therapy be initiated with Benzoyl Peroxide Gel 5%, applying the medication to the affected areas once a day during the first week, and twice a day thereafter as tolerated. Frequency of use should be adjusted to obtain the desired clinical response. Therapy with Benzoyl Peroxide Gel 10% may be initiated in patients who demonstrate accommodation to Benzoyl Peroxide Gel 5%.

Gentle cleansing of the affected areas prior to application of Benzoyl Peroxide Gel 5% or 10% may be beneficial.

Clinically visible improvements will normally occur by the third week of therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continuing use of the drug is normally required to maintain a satisfactory clinical response.

HOW SUPPLIED

Benzoyl Peroxide Gel 5% (Hydroalcoholic Base Acne Gel) are supplied in 60 gram tubes.

Benzoyl Peroxide Gel 5% NDC 21695-686-60

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

MANUFACTURED BY

STIEFEL LABORATORIES, INC.

CORAL GABLES, FL 33134

DISTRIBUTED BY

PERRIGO®

ALLEGAN, MI 49010

Rev. 10/08

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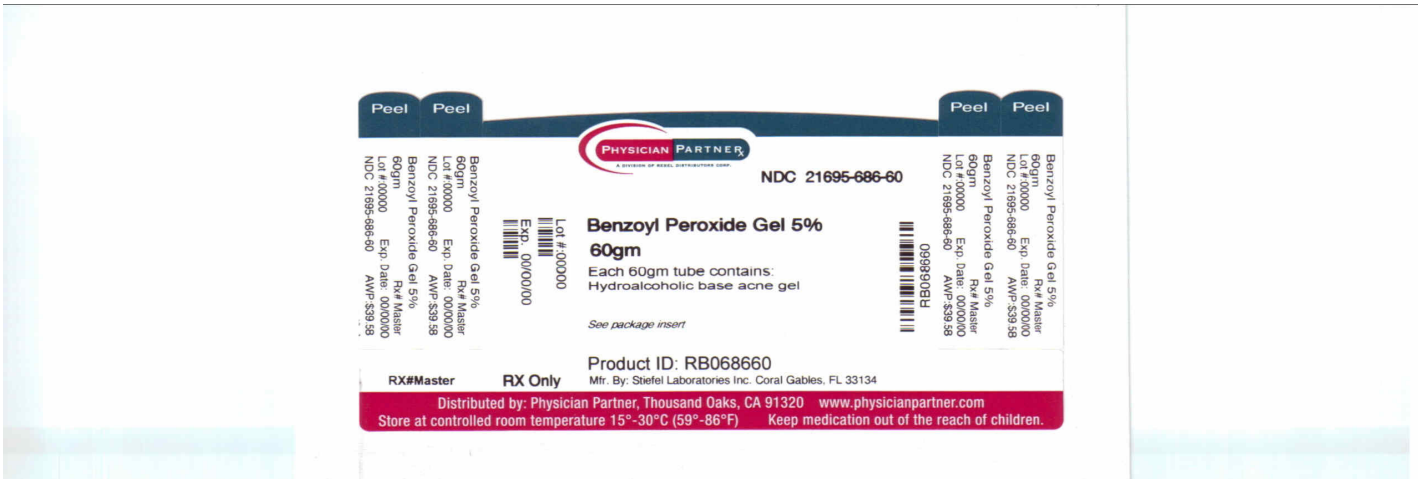
: 9X300 RC J2

Repackaged by:

REBEL DISTRIBUTORS CORP

Thousand Oaks, CA 91320

Principal Display Panel



PERRIGO BENZOYL PEROXIDE HYDROALCOHOLIC BASE

benzoyl peroxide gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-686(NDC:45802-995)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	

Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-686-60	1 in 1 CARTON		
1		60 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		10/04/2007	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 1/2011 Rebel Distributors Corp