BENZOYL PEROXIDE- benzoyl peroxide liquid
Harris Pharmaceutical, 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.

BENZOYL PEROXIDE TOPICAL WASH 10%

DRUG FACTS

Active Ingredient

10% benzoyl peroxide USP

Purpose

Acne medication

Use

- For the treatment of acne

Warnings

For external use only.

- Avoid contact with eyes, eyelids, lips and mucous membranes.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product

- **Avoid unnecessary sun exposure and use a sunscreen.**
- Avoid contact with eyes, lips, and mouth.
- Avoid contact with hair or 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

SHAKE WELL.

- Clean the skin thoroughly before applying this product.
- One to three times daily, wet skin and cover the entire affected area with a thin layer, liberally applying to areas to be cleansed. Massage gently into skin for 10-20 seconds working into a full lather, 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 application to once a day or every other day.
- **If going outside, apply sunscreen after using this product.**
- Follow directions in the sunscreen labeling.
- If irritation or sensitivity develops stop use of both products and ask a doctor.

Other information

Store at controlled room temperature, 15° - 25°C (59° - 77°F)

Inactive Ingredients

Carbomer interpolymer type A NF, cetyl alcohol NF, disodium oleamido MEA-sulfosuccinate, edetate disodium USP, glycerin USP, glyceryl stearate/PEG-100 stearate, laureth-12, magnesium aluminum silicate NF, propylene glycol USP, purified water USP, sodium coco-sulfate, sodium lauroamphoacetate, and xanthan gum NF.

Manufactured for:
Harris Pharmaceutical, Inc.,
Fort Myers, Florida 33908
Manufactured by:
Groupe Parima
Montreal, QC
H4S 1X6 CANADA Rev 06/11

PRINCIPAL DISPLAY PANEL - 148 g Bottle Label

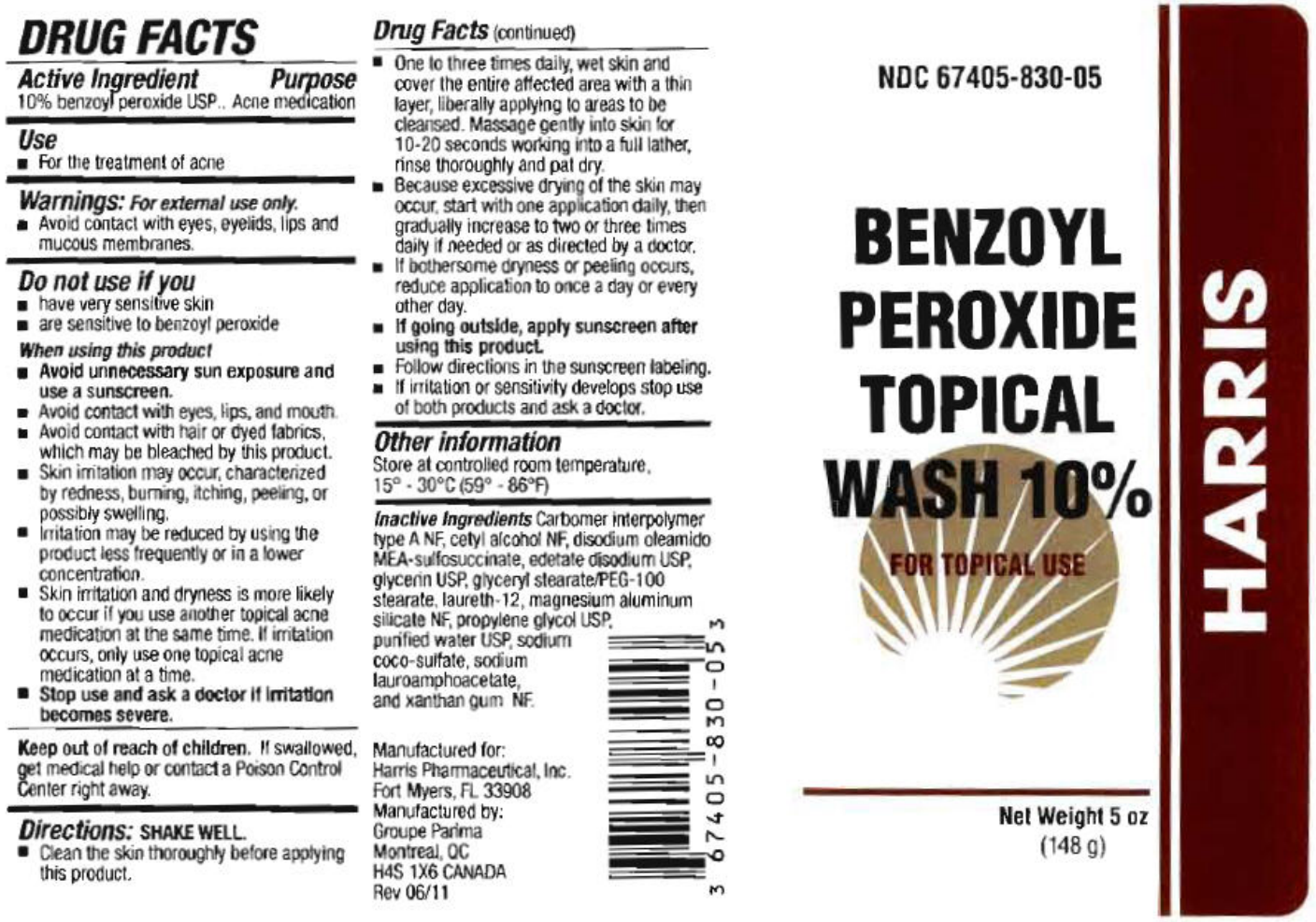
NDC 67405-830-05

BENZOYL
PEROXIDE
TOPICAL
WASH 10%

FOR TOPICAL USE

Net Weight 5 oz
(148 g)

HARRIS



BENZOYL PEROXIDE

benzoyl peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67405-830
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**
cetyl alcohol (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
laureth-12 (UNII: OAH19558U1)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
propylene glycol (UNII: 6DC9Q167V3)	

water (UNII: 059QF0KO0R)	
sodium coco-sulfate (UNII: 3599J29ANH)	
sodium lauroamphoacetate (UNII: SLK428451L)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	WHITE (viscous)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67405-830-05	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2011	
2	NDC:67405-830-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	11/18/2011	

Labeler - Harris Pharmaceutical, Inc. (617204370)

Establishment

Name	Address	ID/FEI	Business Operations
Groupe Parima Montreal		252437850	MANUFACTURE(67405-830)

Revised: 12/2019 Harris Pharmaceutical, Inc.