### BENZOYL PEROXIDE - benzoyl peroxide Wal-Mart 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.

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### drug facts

**Purifying Cleanser** 

Active ingredient Purpose

Benzoyl Peroxide 2.5%......Acne Treatment

Purifying Cleanser

Active ingredient Purpose

Benzoyl Peroxide 2.5%.....Acne Treatment

Use for the management of acne

Purifying Cleanser Warning Section

Warnings

For external use only

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

Ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.
- keep away from lips and mouth
- aviod unnecessary sun exposure and use a sunscreen

Stop use and ask a doctor if skin irritation occurs.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Purifying Cleanser Directions Section

Directions

- Use morning and night. Apply a small (dime sized) amount to dampened skin and gently massage for

1 to 2 minutes.

- Rinse thoroughly with warm water
- Pat dry
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day
- If going outside, use a sunscreen

Other information

- This product may bleach hair or dyed fabrics
- Avoid storing at extreme temperatures (below 40 degrees F and above 100 degrees F)

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### Purifying Cleanser inactive ingredients section

Inactive Ingredients
purified water, disodium PEG-12 dimethicone
sulfosuccinate, magnesium aluminum silicate,
gyyceryl stearate, tridecyl stearate, neopentyl
glycol dicaprylate/dicaprate, tridecyl trimelliate,
PEG-100 Stearate, sorbitol, dimethyl isosorbide,
polyethylene, cetyl esters, anthemis nobilis flower
extract, xanthan gum, propylene glycol,
imidazolidinyl urea, sodium hyaluronate, sodium
PCA, methylparaben, propylparaben, fragrance



### Acne Treatment System

Compare to Proactiv® Solution Active Ingredients\*



Cleanse, Soothe and Moisturize SIMPLE 3 STEP SYSTEM

Cleanser 4 FL OZ (120 mL)
Toner 4 FL OZ (120 mL)
Benzoyl Peroxide Lotion 2 FL OZ (60 mL)

### **Acne Treatment System**

3 Step System



### **Purifying Cleanser**

### **Drug Facts**

Active Ingredient Benzoyl Peroxide 2.5%... Purpose Acne treatment

Use for the management of acne

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#### Directions

- Use morning and night. Apply a small (dime-sized) amount to dampened skin and gently massage for 1 to 2 minutes
- Rinse thoroughly with warm water
- Pat dry
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- If going outside, use a sunscreen

#### Other information

- This product may bleach hair or dyed fabrics
- Avoid storing at extreme temperatures (below 40° F and above 100° F)

### Inactive ingredients

purified water, disodium PEG-12 dimethicone sulfosuccinate, magnesium aluminum silicate, glyceryl stearate, tridecyl stearate, neopentyl glycol dicaprylate/dicaprate, tridecyl trimelliate, PEG-100 stearate, sorbitol, dimethyl isosorbide, polyethylene, cetyl esters, anthemis nobilis flower extract, xanthan gum, propylene glycol, imidazolidinyl urea, sodium hyaluronate, sodium PCA, methylparaben, propylparaben, fragrance



### Rejuvenating Toner

#### **Directions:**

Apply to cleansed skin with a cotton ball or pad, morning and night as needed. Allow Rejuvenating Toner to dry and follow with Repairing Lotion.

Warnings: For external use only. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If going outside, use a sunscreen. If irritation or sensitivity develops, discontinue use and consult a doctor. Avoid storing at extreme temperatures (below 40° F and above 100° F).

Inactive ingredients: purified water, glycolic acid, hamamelis virginiana (witch hazel) leaf extract, glycerin, anthemis nobilis flower extract, rosa canina fruit extract, aloe barbadensis leaf extract, sodium PCA, panthenol, polysorbate 20. propylene glycol, allantoin, hydroxyethyl-cellulose, sodium hydroxide, imidazolidinyl urea, benzophenone-4, tetrasodium EDTA, methylparaben, fragrance, propylparaben, blue 1, yellow 5

- helps remove dead skin cells and impurties
- fights existing blemishes and helps prevent new blemishes



Satisfaction guaranteed -Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716

Wal-Mart Stores, Inc.

\*This product is not manufactured or distributed by Guthy-Renker, LLC, owner of the registered trademark Proactiv®.

### 3 Moisturize

### Repairing Lotion

### **Drug Facts**

Active ingredient Benzoyl Peroxide 2.5%... Purpose Acne treatment

Use for the management of acne

### Warnings

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Stop use and ask a doctor if skin irritation occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Cleanse the skin thoroughly before applying medication
- Cover the entire affected area with a thin layer 1 to 3 times daily
- Because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 or 3 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, use a sunscreen

#### Other information

- This product may bleach hair or dyed fabrics
- Avoid storing at extreme temperatures (below 40° F and above 100° F)

### Inactive ingredients

purified water, cetearyl alcohol, ceteareth-20, ethoxydiglycol, cyclotetrasiloxane, propylene glycol, dimethicone, glyceryl stearate, cyclopentasiloxane, diazolidinyl urea, methylparaben, propylparaben, PEG-100 stearate, panthenol, allantoin, triethanolamine, carbomer, fragrance, xanthan gum

## This Kit Contains



**Purifiying Cleanser** 

· Contains 2 5% Renzovi

peroxide as a key anti-bacterial agent to fight acne

- Tiny beads remove dead skin cells and impurities to help prevent clogged pores
- Enhanced with soothing botanicals



### Rejuvenating Toner

- Alcohol-free formula helps skin look & feel refreshed
- Helps to remove excess oil and leaves skin feeling softer
- · Formula holne to

### balance skin tone

# (3) Moisturize

### Repairing Lotion

- Contains 2.5%

   Benzoyl peroxide to
   help dry up blackheads
   and blemishes before
   they form
- Micro-Crystalline formula penetrates pores to help prevent future breakouts
- Oil-free formula

### Repairing Lotion

Active ingredient Purpose Benzoyl Peroxide 2.5%.....Acne Treatment

Use for the management of acne Repairing Lotion Warning Section

Warnings

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Repairing Lotion Directions Section

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- If going outside, use a sunscreen

Other information

- This product may bleach hair or dyed fabrics
- Avoid storing at extreme temperatures (below 40 degrees F and above 100 degrees F)

Repairing Lotion inactive ingredients section

Inactive ingredients purified water, cetearyl alcohol, ceteareth-20, ethoxydiglycol, cyclotetrasiloxane, propylene glycol, dimethicone, glyceryl stearate, cyclopentasiloxane diazolidinyl urea, methylparaben, propylparaben, PEG-100 stearate, panthenol, allantoin, triethanolamine, carbomer, fragrance, xanthan gum

### **BENZOYL PEROXIDE**

benzoyl peroxide kit

### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:49035-021

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l	# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>		
l	1 NDC:49035-021-13	1 in 1 KIT				

### **Ouantity of Parts**

Q cacara	Quantity of Larts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE, PLASTIC	120 mL		
Part 2	1 BOTTLE, PLASTIC	60 mL		

### Part 1 of 2

### **BENZOYL PEROXIDE**

benzoyl peroxide cream

### **Product Information**

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

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	Ingredient Name	<b>Basis of Strength</b>	Strength	
	<b>BENZOYL PEROXIDE</b> (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII: W9 WZN9 A0 GM)	BENZO YL PERO XIDE	36.9 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
PEG-12 STEARATE (UNII: 9KU38O8CEK)	
SORBITOL (UNII: 506T60A25R)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
NEOPENTYL GLYCOL (UNII: Q180 HXD6 S5)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
XANTHAN GUM (UNII: TTV12P4NEE)	
IMIDUREA (UNII: M629807ATL)	
METHYLPARABEN (UNII: A218 C7H19 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		120 mL in 1 BOTTLE, PLASTIC				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333D	02/26/2010			

### Part 2 of 2

### **BENZOYL PEROXIDE**

benzoyl peroxide lotion

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
BENZO YL PERO XIDE (UNII: W9 WZN9 A0 GM) (BENZO YL PERO XIDE - UNII: W9 WZN9 A0 GM)	BENZOYL PEROXIDE	36.9 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118 X02B)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
PANTHENOL (UNII: WV9CM0O67Z)		
ALLANTO IN (UNII: 344S277G0Z)		
XANTHAN GUM (UNII: TTV12P4NEE)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
POLYOXYL 100 STEARATE (UNII: YD0 1N1999R)		
TROLAMINE (UNII: 9O3K93S3TK)		

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		60 mL in 1 BOTTLE, PLASTIC				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	02/26/2010	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333D	02/26/2010			

### **Labeler** - Wal-Mart Stores Inc (051957769)

### Registrant - Pharma Pac, LLC (140807475)

Establishment					
Name	Address	ID/FEI	Business Operations		
Pharma Pac, LLC		140807475	manufacture		

Revised: 2/2011 Wal-Mart Stores Inc