## SKIN PHARMACY ADVANCED ACNE THERAPY TARGETED TREATMENT WIPES - benzoyl peroxide swab

#### AMCOL Health & Beauty Solutions, Inc. DBA

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**

#### **Active Ingredient**

Benzoyl Peroxide 2.5%

#### **Purpose**

Acne Treatment

#### Uses

for the management of acne

#### Warnings

#### For external use only

#### Do not use if you

- Have very sensitive skin
- Are sensitive to benzoyl peroxide

**Ask a doctor of pharmacist before use if you are** using other topical acne medications at the same time or immediately following use of this product.

#### When using this product

- Avoid unnecessary sun exposure and use a sunscreen.
- Avoid contact with lips, eyes, or mouth.
- Skin irritation may occur, characterized by redness, burning, itching, peeling, or possible swelling.
- Irritation may be reduced by using the product less frequently or in lower concentration.
- Avoid contact with hair and dyed fabrics, which may be bleached by this product.

#### **Stop use and ask a doctor if** irritation becomes severe.

**Keep out of reach of children.** Do not swallow. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Clean the skin thoroughly before applying this product.
- Start with one application daily then gradually increase to 2-3 times daily as needed.
- If going outside apply sunscreen after using this product.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- Avoid storing at extreme temperatures (below 40°F and above 100°F).

#### **Inactive ingredients**

Water, Caprylic/Capric Triglyceride, Propanediol, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Dimethicone, Cyclopentasiloxane, Steareth-20, Cyclohexasiloxane, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, Xanthan Gum, Cetearyl Alcohol, Bentonite, Citric Acid, Sodium Citrate, Disodium EDTA, Ethylhexylglycerin, Sodium Hydroxide, Allantoin, Chamomilla Recutita (Matricaria) Flower Oil, Panthenol

Microsponge<sup>®</sup> is a registered trademark of AMCOL International Corp.

Save carton for complete labeling

M050735

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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FP415

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## Principal Display Panel - Skin+Pharmacy Advanced Acne Therapy Targeted Treatment Wipes Label

**SKIN+PHARMACY** 

**ADVANCED** 

**ACNE THERAPY** 

# TARGETED TREATMENT WIPES with Microsponge® Technology

2.5% Benzoyl Peroxide

- effectively kills acne-causing bacteria
- promotes healthier, clearer skin
- fragrance free

#### **DERMATOLOGIST TESTED**

exclusively at

CVS/pharmacy

10 pre-moistened wipes • 3.5 x 3 in (8.9 x 7.6 cm)

M050744



## Principal Display Panel - Skin+Pharmacy Advanced Acne Therapy Targeted Treatment Wipes Carton Label

#### SKIN+PHARMACY

ADVANCED

ACNE THERAPY

## TARGETED TREATMENT WIPES with Microsponge® Technology

2.5% Benzoyl Peroxide

- effectively kills acne-causing bacteria
- promotes healthier, clearer skin
- fragrance free

#### **DERMATOLOGIST TESTED**

exclusively at

CVS/pharmacy

2 packs/10 wipes each • Total 20 pre-moistened wipes

 $3.5 \times 3 \text{ in } (8.9 \times 7.6 \text{ cm})$ 



# SKIN PHARMACY ADVANCED ACNE THERAPY TARGETED TREATMENT WIPES

benzoyl peroxide swab

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68634-068	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
benzoyl peroxide (UNII: W9WZN9A0GM) (benzoyl peroxide - UNII:W9WZN9A0GM)	benzoyl peroxide	25 mg in 1 mL	

water (UNII: 059QF0KO0R) medium-chain triglycerides (UNII: C9H2L21V7U)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
propanediol (UNII: 5965N8W85T)	
methyl methacrylate/glycol dimethacrylate crosspolymer (UNII: EG97988M5Q)	
dimethicone (UNII: 92RU3N3Y1O)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
steareth-20 (UNII: L0Q8IK9E08)	
cyclomethicone 6 (UNII: XHK3U310BA)	
glyceryl monostearate (UNII: 230 O U9 XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
phenoxyethanol (UNII: HIE492ZZ3T)	
kanthan gum (UNII: TTV12P4NEE)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
bentonite (UNII: A3N5ZCN45C)	
citric acid monohydrate (UNII: 2968PHW8QP)	
sodium citrate (UNII: 1Q73Q2JULR)	
sodium hydroxide (UNII: 55X04QC32I)	
edetate disodium (UNII: 7FLD91C86K)	
ethylhexylglycerin (UNII: 147D247K3P)	
allantoin (UNII: 344S277G0Z)	

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68634-068- 01	2 in 1 CARTON	05/01/2014		
1		10 in 1 PACKET			
1		1.4 mL in 1 APPLICATOR; 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	05/01/2014	

### **Labeler** - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment			
Name	Address	ID/FEI	Business Operations
$\begin{array}{lll} AMCOL \; Health \; \& \; Beauty \; Solutions, \\ Inc. \; DBA \end{array}$		872684803	MANUFACTURE(68634-068), PACK(68634-068), LABEL(68634-068), ANALYSIS(68634-068)