

## ON TARGET- benzoyl peroxide gel CoValence, 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.*

### OTC Drug Facts On Target BPO Cleanser

#### Principal Display Panel

##### On Target BPO Cleanser

Benzoyl Peroxide 10%

<b>Drug Facts</b>
<b>Active Ingredient(s):</b> Benzoyl Peroxide 10%
<b>Purpose:</b> Acne Treatment
<b>Use:</b> Anti-bacterial cleanser for the treatment of acne and acne prone skin
<b>Warnings:</b> For external use only. Keep out of reach of children. When using this product <ul style="list-style-type: none"><li>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</li></ul> Do not use if you <ul style="list-style-type: none"><li>have very sensitive skin</li><li>are sensitive to benzoyl peroxide</li></ul> When using this product <ul style="list-style-type: none"><li>avoid unnecessary sun exposure and use a sunscreen</li><li>avoid contact with the eyes, lips, and mouth</li><li>avoid contact with hair and dyed fabrics, which may be bleached by this product</li><li>skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation maybe reduced by using the product less frequently or in a lower concentration</li><li>Stop use and ask a doctor if irritation becomes severe</li></ul>
<b>Directions:</b> <ul style="list-style-type: none"><li>When using this product apply only to areas with acne.</li><li>If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.</li></ul>
<b>Ingredients:</b> Cocamidopropyl Betaine, Aqua (Water), Sodium Coco-Glucoside Tartrate, Decyl Glucoside, Sodium Lauroyl Lactylate, Polyacrylate-1 Crosspolymer, Sodium Methyl Cocoyl Taurate, Hydroxypropyl Methylcellulose, Cymbopogon Schoenanthus (Lemongrass) Oil*, Magnesium Aluminum Silicate, Glycolic Acid, Hamamelis Virginiana (Witch Hazel) Water, Caprylyl Glycol, 1,2-Hexanediol, Potassium Sorbate, Citric Acid, Alcohol, Tropolone *Certified Organic Ingredient

#### Active Ingredients :

Benzoyl Peroxide 10%

#### Purpose :

Acne Treatment

#### Warnings :

Children under 12 years of age: Do not use, consult a physician.

#### Warnings :

For external use only. Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. Contact with any colored material (including hair and fabric) may result in blanching or discoloration. If excessive irritation develops, discontinue use and consult your

physician.

**Directions:**

Adults and children 12 years of age or older: Apply to the affected are no more than 3 to 4 times daily.

**Ingredients:**

Cocamidopropyl Betain, Aqua (Water), Sodium Coco-Glucoside Tartrate, Decyl Glucoside, Sodium Lauroyl Lactylate, Polyacrylate-1 Crosspolymer, Sodium Methyl Cocoyl Taurate, Hydroxypropyl Methylcellulose, Cymbopogon Schoenathus (Lemongrass) Oil\*, Magnesium Aluminum Silicate, Glycolid Acid, Hamamelis Virginiana (Witch Hazel) Water, Caprylyl Glycol, 1,2-Hexanediol, Potassium Sorbate, Citric Acid, Alcohol, Tropolone

\*Certified Organic

**Uses:**

Antibacterial cleanser for the treatment of acne and acne prone skin.

<b>ON TARGET</b>			
benzoyl peroxide gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66915-437
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)		BENZOYL PEROXIDE	0.102 g in 1 g
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)			1 g in 1 g
Water (UNII: 059QF0KO0R)			1 g in 1 g
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)			1 g in 1 g
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)			1 g in 1 g
WITCH HAZEL (UNII: 101I4J0U34)			1 g in 1 g
1,2-HEXANEDIOL (UNII: TR046Y3K1G)			1 g in 1 g
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)			1 g in 1 g
CYMBOGON SCHOENANTHUS LEAF (UNII: XF54B1Z2HF)			1 g in 1 g
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			1 g in 1 g
GLYCOLIC ACID (UNII: 0WT12SX38S)			1 g in 1 g
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			1 g in 1 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			1 g in 1 g
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			1 g in 1 g
ALCOHOL (UNII: 3K9958V90M)			1 g in 1 g
TROPOLONE (UNII: 7L6DL16P1T)			1 g in 1 g

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66915-437-01	200000 g in 1 DRUM; Type 0: Not a Combination Product	08/18/2011	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	08/18/2011	

**Labeler** - CoValence, Inc. (070653204)**Registrant** - CoValence, Inc (070653204)**Establishment**

Name	Address	ID/FEI	Business Operations
CoValence, Inc.		070653204	manufacture(66915-437)

Revised: 4/2015

CoValence, Inc.