

## **CONTROLLING CREAM- benzoyl peroxide cream CA-BOTANA INTERNATIONAL**

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**Controlling Cream**

**Warnings:**

For external use only.

Do not use on wounds or damaged skin

When using this product: use only as directed. Avoid contact with eyes. Do not bandage tightly

Stop use and ask a doctor if: redness is present. Irritation develops. Condition worsens or symptoms persist more than 7 days. Symptoms clear up and occur again within a few days.

Store at room temperature. Lot number and expiration date see crimp or see box.

cleanse the skin thoroughly with soft foam deep cleanse before applying. cover the entire affected area with a thin layer 1 to 2 times daily. because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 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. Allow benzoyl peroxide to dry the follow directions on sunscreen label.

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Alpha Oligo Peptide-6 TM  
Calendula officinalis (Marigold) Extract  
Cetearyl Alcohol  
Cetearyl Isononanoate  
Cynamomum Zeylanicum  
Ethylhexylglycerin  
Glycerine  
Glycine  
Hydrogen Peroxide  
Mineral oil  
Oenothera biennis (Evening Primrose) extract  
Panicum Miliaceum (Millet) extract  
Petrolatum  
Phenoxyethanol  
Phosphatidylcholine  
Polysorbate 60  
Potassium Sorbate  
Rosa canina (Rosehip) extract  
Rosmarinus officinalis (Rosemary) extract  
Sorbitan Stearate  
Tetra Sodium  
Water (Aqua)

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

Center immediately.

when using this product apply to affected areas only. avoid unnecessary sun exposure and use a sunscreen. do not use in or near eyes. using other topical acne drugs at the same time or right

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DOCTOR D.  
SCHWAB®

# CONTROLLING CREAM

CRÈME RÉGULATRICE  
CREMA CONTROLANTE



**ACNE +  
OILY SKIN**



1 FL OZ / 30 ML



### Drug Facts

Active ingredient	Purpose
Benzoyl Peroxide 2.7%	Acne Treatment

**Uses** •cleas acne pimples •helps prevent new acne pimples •penetrates pores to eliminate most acne blemishes, blackheads, and whiteheads

### Warnings For external use only

**Do not use** •on broken skin •on large areas of the body

**When using this product** •apply to affected areas only •avoid unnecessary sun exposure and use a sunscreen •do not use in or near eyes •using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless

NDC # 36192-017-05

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A Division of CA BOTANICA  
San Diego, CA 92121, USA  
Made in USA

REF #860

Peel Here

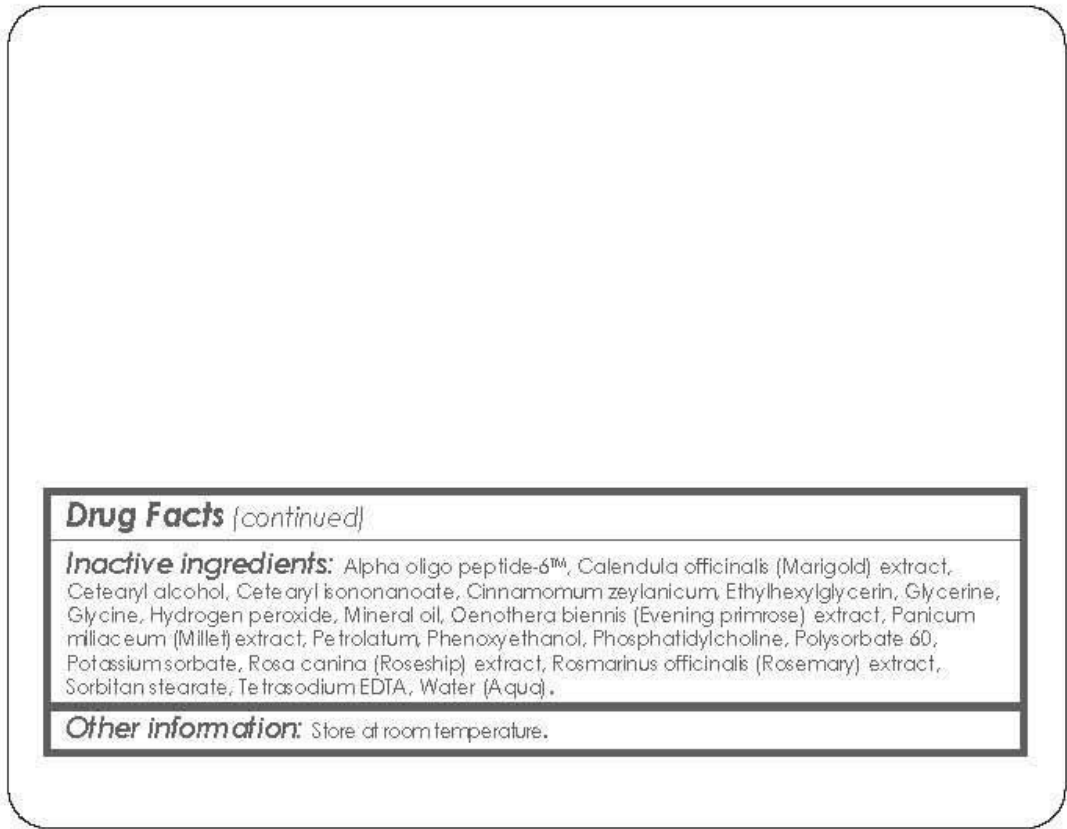
### Drug Facts (continued)

directed by a doctor.

**Stop use and ask a doctor if** too much skin irritation or sensitivity develops or increases

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

**Directions** •cleanse the skin thoroughly with Soft Foam Deep Cleanse before applying •cover the entire affected area with a thin layer 1 to 2 times daily •because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 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. Allow benzoyl peroxide to dry, the follow directions on sunscreen label.



**Package label display panel**

<b>CONTROLLING CREAM</b>			
benzoyl peroxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35192-017
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOYL PEROXIDE</b> (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)		BENZOYL PEROXIDE	0.8 mg in 29.6 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CINNAMON</b> (UNII: 5S29HWU6QB)	
<b>CINNAMON LEAF OIL</b> (UNII: S92U8SQ71V)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCINE</b> (UNII: TE7660XO1C)	
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>OENOTHERA BIENNIS</b> (UNII: 76UI55V071)	
<b>MILLET</b> (UNII: TJR6B3R47P)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>ROSA CANINA LEAF</b> (UNII: J3N2Z889QP)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-017-05	29.6 mg in 1 TUBE; Type 0: Not a Combination Product	11/02/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	11/09/2014	

**Labeler** - CA-BOTANA INTERNATIONAL (106276728)

**Registrant** - RODOLFO UGELSTAD (106276728)

## Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-017)