SAFEWAY ACNE TREATMENT- benzoyl peroxide cream SAFEWAY 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.

DRUG FACTS

ACTIVE INGREDIENT

BENZOYL PEROXIDE 10%

PURPOSE

ACNE MEDICATION

USES

FOR THE TREATMENT AND PREVENTION OF ACNE PIMPLES.

WARNINGS

FOR EXTERNAL USE ONLY. SUNSCREEN ALERT: AVOID UNNECESSARY SUNSCREEN EXPOSURE BY USING A SUNSCREEN.

DO NOT USE IF

YOU HAVE VERY SENSITIVE SKIN OR ARE SENSITIVE TO BENZOYL PEROXIDE OR IF YOU ARE TAKING OTHER TOPICAL ACNE MEDICATIONS AT THE SAME OR IMMEDIATELY FOLLOWING USE OF THIS PRODUCT. ONLY ONE MEDICATION SHOULD BE USED UNLESS DIRECTED BY A DOCTOR.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES, LIPS AND MOUTH. AVOID CONTACT WITH HAIR OR DYED FABRICS, INCLUDING CARPET AND CLOTHING WHICH MAY BE BLEACHED BY THIS PRODUCT. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

SKIN IRRITATION, REDNESS, BURNING, ITCHING, PEELING OR SWELLING OCCURS AND LASTS. MILD IRRITATION MAY BE REDUCED BY USING THE PRODUCT LESS FREQUENTLY OR IN A LOWER CONCENTRATION.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

CLEANSE THE SKIN THOROUGHLY BEFORE APPLYING MEDICATION. COVER THE ENTIRE AFFECTED AREA WITH A THIN LAYER 1 TO 3 TIMES A DAY. START WITH 1 APPLICATION DAILY AND GRADUALLY INCREASE TO 2 TO 3 TIMES DAILY IF NEEDED OR AS DIRECTED BY A DOCTOR. IF PEELING OCCURS, REDUCE APPLICATION TO ONCE A DAY OR EVERY OTHER DAY. WHEN GOING OUTSIDE, USE A SUNSCREEN. ALLOW

CREAM TO DRY AND FOLLOW DIRECTIONS IN THE SUNSCREEN LABELING. IF IRRITATION DEVELOPS, DISCONTINUE USE OF BOTH PRODUCTS AND CONSULT A DOCTOR.

OTHER INFORMATION

KEEP CAP TIGHTLY CLOSED. STORE AT CONTROLLED ROOM TEMPERATURE 20-25C (68-77F).

INACTIVE INGREDIENTS:

WATER (AQUA), C12-15 ALKYL BENZOATE, PROPYLENE GLYCOL, GLYCERYL STEARATE SE, BENTONITE, LAURETH-7, CARBOMER, ALUMINUM HYDROXIDE, PEG-12, ISOPROPYL MYRISTATE, METHYLPARABEN, PROPYLPARABEN.

QUESTIONS OR COMMENTS?

1-888-723-3929

LABEL COPY



Questions or comments? 1-888-723-3929 Inscrive ingredients: Water (Aqua), C12-15 Alkyl Benzoate, Propylene Glycol, Glyceryl Stearate SE, Bentonite, Laureth-7. Carbomer, Aluminum Hydroxide, PEG-12, Isopropyl Myristate, Methylparaben, Propylparaben, Other information = Keep cap tightly closed. = Store at controlled room temperature 20°-25°C (68°-77°F). follow directions in the sunscreen Isbeling. If in itsiton develops, discontinue use of both products and consult a doctor peeling occurs, reduce application to once a day or every other day. = When going outside, use a sunscreen, Allow cream to dry and Directions = Cleanse the skin thoroughly before applying medication. = Cover the entire affected area with a thin layer 1 to 3 times a day. = Start with 1 application daily and gradually increase to 2 to 3 times daily if needed or as directed by a doctor, = If Keep out of reach of children. = In case of accidental ingestion, get medical help or contact a Poison Control Center immediately. Mild irritation may be reduced by using the product less frequently or in a lower concentration clothing which may be bleached by this product. = If contact occurs, rinse thoroughly with water. When using this product = avoid contact with eyes, lips and mouth. = Avoid contact with hair or dyed fabrics, including carpet and at the same time or immediately following use of this product. Only one medication should be used unless directed by a doctor. For external use only. Sunscreen alert, avoid unnecessary sunscreen exposure by using a sunscreen.

Do not use if = you have very sensitive skin or are sensitive to Benzoyl Peroxide = or if you are taking other topical acne medications from the use of the proceeding of the use of the process of the proces Uses For the treatment and prevention of acne pimples. непезираш апря Benzoyl Peroxide Purpose Active ingredient Drug Facts

SAFEWAY ACNE TREATMENT

benzoyl peroxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-826
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
BENZO YL PERO XIDE (UNII: W9 WZN9 A0 GM) (BENZO YL PERO XIDE - UNII: W9 WZN9 A0 GM)	BENZOYL PEROXIDE	10 g in 100 g			

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)			
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)			
BENTO NITE (UNII: A3N5ZCN45C)			
LAURETH-7 (UNII: Z95S6G8201)			
CARBOMER 934 (UNII: Z135WT9208)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)			
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-826-01	28 g in 1 TUBE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333D	06/06/2012			

Labeler - SAFEWAY INC. (009137209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture	

Revised: 6/2012 SAFEWAY INC.