

ACNE CLEARING TREATMENT FACE- sulfur, benzoyl peroxide, salicylic acid liquid
CarePlus Pharma S.A. de C.V.

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.

Active Ingredient.....	Purpose
Sulphur 5%.....	Acne medication
Benzoyl Peroxide 2.5%.....	Acme medication
Salicylic acid 2%.....	Acne medication

Uses:For the management of acne

- helps clear up acne blemishes, black heads, helps prevent the development of new acne pimples
- penetrates pores to reduce the number of acne pimples, white heads and black heads
- help keep skin clear of new acne pimples, white heads and black heads
- helps prevent new acne pimples, white heads and black heads from forming
- help prevent the development of new pimples, white heads and black heads

Warnings: For external use only.

Do not use

- if you have sensitive skin and/or are sensitive to [active ingredient]

When using this product

- 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
- avoid unnecessary sun exposure and use sun screen, Acne Clearing Moisture with SPF 45
- skin irritation may occur, characterized by redness, burning, itching, peeling, and possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration

Stop use and ask a doctor if

irritation becomes severe

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

Directions:

1. Acne Clearing Cleanser
2. Acne Clearing Tonic
3. Acne Clearing Treatment 101

Ingredients: Purified Water, Ethyl Alcohol, Hamammelis Extract, Chamomile Extract, Salicyl Alcohol, Ethhylene Glycol, Propylene Glycol, Dodecyl Benzene Sulfonate, EDTA, Methylparaben, Propylparaben. Purified Water, Sulfer, Catalase, Aqueous extract of arnica, Glycerin, Cetyl Alcohol, Ceteareth-12, Bromelain, Ultrez 21, Mineral Oil, Ethhylene Glycol, Propylene Glycol, Sodium Ascorbyl Phosphate, Triethanolamine, Ascorbic Acid, Dodecyl Benzene Sulfonate, Peppermint oil, Piperine, Mint Base, EDTA, BHT, BHA, Methylparaben, Propylparaben. Purified Water, Sulfer, Catalase, Aqueous extract of arnica, Glycerin, Cetyl Alcohol, Ceteareth-12, Bromelain, Ultrez 21, Mineral Oil, Ethhylene Glycol, Propylene Glycol, Sodium Ascorbyl Phosphate, Triethanolamine, Ascorbic Acid, Dodecyl Benzene Sulfonate, Peppermint oil, Piperine, Mint Base, EDTA, BHT, BHA, Methylparaben, Propylparaben.

Three Bottles

1. Acne Clearing Cleanser 240 mL

2. Acne Clearing Tonic 120 mL
3. Acne Clearing Treatment 101 60 mL

Acne Clearing Treatment - FACE

ACNE CLEARING TREATMENT FACE

sulfur, benzoyl peroxide, salicylic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51439-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	.012 mg in .024 mg
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	.006 mg in .024 mg
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	.0048 mg in .024 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CATALINA (UNII: T3JI0587Q7)	
ARNICA MONTANA (UNII: O80TY208ZW)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
BROMELAINS (UNII: U182GP2CF3)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
MINERAL OIL (UNII: T5L8T28FGP)	
ETHYLENE GLYCOL (UNII: FC72KVT52F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJK51DR)	
TROLAMINE (UNII: 9O3K93S3TK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
DODECYLBENZENESULFONIC ACID (UNII: 60NSK897G9)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PIPERINE (UNII: U71XL721QK)	
MINT (UNII: FV98Z8G1TP)	
EDETIC ACID (UNII: 9G34HU7RV0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
VITAMIN A (UNII: 81G40H8B0T)	
POMEGRANATE (UNII: 56687D1Z4D)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51439-007-02	3 in 1 BOX		
1	NDC:51439-007-01	.024 mg in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	08/06/2012	

Labeler - CarePlus Pharma S.A. de C.V. (815061551)

Registrant - CarePlus Pharma S.A. de C.V. (815061551)

Establishment

Name	Address	ID/FEI	Business Operations
CarePlus Pharma S.A. de C.V.		815061551	manufacture(51439-007)

Revised: 3/2013

CarePlus Pharma S.A. de C.V.