

BLEMISH CORRECTING SERUM SENSITIVE- salicylic acid gel
CEN BEAUTY LLC

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

SALICYLIC ACID 2%

PURPOSE

ACNE TREATMENT

USES

- TREATS ACNE
- DRIES UP ACNE PIMPLES
- HELPS PREVENT NEW ACNE PIMPLES

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE

- IF YOU HAVE VERY SENSITIVE SKIN
- ARE SENSITIVE TO BENZOYL PEROXIDE

WHEN USING THIS PRODUCT

- SKIN IRRITATION MAY OCCUR, CHARACTERIZED BY REDNESS, BURNING, ITCHING, PEELING, OR POSSIBLY SWELLING. IRRITATION MAY BE REDUCED BY USING THE PRODUCT LESS FREQUENTLY OR IN A LOWER CONCENTRATION.
- 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.

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

- ON CLEAN AND DRY SKIN, APPLY A SMALL AMOUNT EVENLY OVER THE AFFECTED AREAS.
- AVOID THE DELICATE EYE AREA.
- START WITH ONE APPLICATION DAILY THEN GRADUALLY INCREASE TO TWO 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.
- CONSULT A PHYSICIAN BEFORE USE.

Other Information

Store at 20-25 DEGREES CELCIUS (68-78 DEGREES FAHRENHEIT)

INGREDIENTS

aqua (water), ethoxydiglycol, butylene glycol, glycereth-7 trimethyl ether, aminomethylpropanol,

potassium azeloyl, diglycinate, syringa vulgaris (lilac) leaf cell culture extract, dipotassium glycyrrhizate, urea, angelica sinensis extract, avena sativa (oat) extract, avena sativa (oat) kernel extract, hamamelis virginiana (witch hazel) , bark/leaf/twig extract, papain, betaine, calcium pantothenate, proline, Alanine, serine, magnesium lactate, potassium lactate, lecithin, glycerin, maltodextrin , ethylhexylglycerin, sodium citrate, xanthan gum, hydroxyethylcellulose, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, magnesium chloride, benzyl alcohol , sorbic acid, caprylyl glycol, phenoxyethanol, ethylhexylglycerin

<p>Drug Facts</p>	<p>Drug Facts (continued)</p>				
<table border="0"> <tr> <td style="width: 50%;">Active ingredient</td> <td style="width: 50%;">Purpose</td> </tr> <tr> <td>Salicylic Acid 2%.....</td> <td>Acne Treatment</td> </tr> </table>	Active ingredient	Purpose	Salicylic Acid 2%.....	Acne Treatment	<p>Directions</p> <ul style="list-style-type: none"> ▪ On clean and dry skin, apply a small amount evenly over the affected areas. ▪ Avoid the delicate eye area. ▪ Start with one application daily then gradually increase to two 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. ▪ Consult a physician before use.
Active ingredient	Purpose				
Salicylic Acid 2%.....	Acne Treatment				
<p>Uses</p> <ul style="list-style-type: none"> ▪ Treats acne ▪ Dries up acne pimples ▪ Helps prevent new acne pimples 	<p>Other Information</p> <ul style="list-style-type: none"> ▪ Store at 20– 25 degrees Celsius (68–78 degrees Fahrenheit) 				
<p>Warnings</p> <p>For external use only</p>	<p>Inactive Ingredients aqua (water), ethoxydiglycol, butylene glycol, glycereth-7 trimethyl ether, aminomethylpropanol, potassium azeloyl, diglycinate, syringa vulgaris (lilac) leaf cell culture extract, dipotassium glycyrrhizate, urea, angelica sinensis extract, avena sativa (oat) extract, avena sativa (oat) kernel extract, hamamelis virginiana (witch hazel) , bark/leaf/twig extract, papain, betaine, calcium pantothenate, proline, Alanine, serine, magnesium lactate, potassium lactate, lecithin, glycerin, maltodextrin , ethylhexylglycerin, sodium citrate, xanthan gum, hydroxyethylcellulose, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, magnesium chloride, benzyl alcohol , sorbic acid, caprylyl glycol, phenoxyethanol, ethylhexylglycerin</p>				
<p>Do not use</p> <ul style="list-style-type: none"> ▪ If you have very sensitive skin 					
<p>When using this product</p> <ul style="list-style-type: none"> ▪ Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration ▪ 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. 					
<p>Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases</p>					
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>					



CLEAR

BLEMISH
CORRECTING
SERUM
SENSITIVE

1 fl oz 30ml e

BLEMISH CORRECTING SERUM SENSITIVE

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54272-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERETH-7 TRIMETHYL ETHER (UNII: XMC7402M60)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
POTASSIUM AZELOYL DIGLYCINATE (UNII: N02RVN6NYP)	
SYRINGA VULGARIS WHOLE (UNII: U49SHU1VCI)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
UREA (UNII: 8W8T17847W)	
ANGELICA SINENSIS WHOLE (UNII: 697D19QDBN)	
AVENA SATIVA TOP (UNII: 1ZX4OXU3N6)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
PAPAIN (UNII: A236A06Y32)	
BETAINE (UNII: 3SCV180C9W)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
PROLINE (UNII: 9DLQ4CIU6V)	
ALANINE (UNII: OF5P57N2ZX)	
SERINE (UNII: 452VLY9402)	
MAGNESIUM LACTATE (UNII: MT6QI8324A)	
POTASSIUM LACTATE (UNII: 87V1KMK4QV)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBIC ACID (UNII: X045WJ989B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54272-103-11	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/21/2013	

Labeler - CEN BEAUTY LLC (078664118)

Registrant - CEN BEAUTY LLC (078664118)

Revised: 2/2013

CEN BEAUTY LLC