# GENTLE REJUVENATION SYSTEM- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone

Obagi Medical Products, Inc., a division of Valeant Pharmaceutcals North America 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.

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#### GENTLE REJUVENATION SYSTEM

## **Drug Facts**

Active ingredients	Purpose	
Avobenzone 3%	Sunscreen	
Homosalate 8%	Sunscreen	
Octisalate 5%	Sunscreen	
Octocrylene 2.79%	Sunscreen	
Oxybenzone 3%	Sunscreen	

### Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

# Warnings

For external use only

**Do not use** on damaged or broken skin

Stop use and ask a doctor if rash occurs

**When using this product** keep out of eyes. Rinse with water to remove.

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

## **Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m.–2 p.m.
  - wear long-sleeved shirts, pants, hats, and sunglasses

## **Inactive ingredients**

ascorbic acid, citrus grandis (grapefruit) peel extract, dimethicone, dimethicone crosspolymer, fragrance, octoxynol-10

# Other information

- store at controlled room temperature: 15°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

# Questions or comments?

1.800.636.7546

Monday–Friday 9 a.m.–4 p.m. Pacific Time Distributed by OMP, Inc., Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

**OBAGI**®

**MEDICAL** 

GENTLE REJUVENATION SYSTEM

Sensitive Skin Kit





GENTLE REJUVENATION SYSTEM



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Sensitive Skin Kit

GENTLE REJUVENATION SYSTEM





Sensitive Skin Kit

Sensitive Skin Kit



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For tified Sunscreen Broad Spectrum SPF 30 With Vikamin C

This broad spectrums unscreen, formulated with 10% Lesconbic acid (Viternin C), MA(g 84) . 50 T.f .1w19M

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	Drug Facts

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gnections: Apply to face twice a day, or as directed by a physician.

Warrange: Avoid getting product into eyes. For external use only. Keep out of or reach of all lideran. I influidion occurs, weath product off, discontinue use, and

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Advanced Night Repair Net wt. 1.7 oz. (50 g) PM

appearance of sun-damaged skin and reduces the visible signs of photodamage. Non-comedogenic and hyposilergenic, Advanced Might Pepalr provides deep hydration while you sleep. The exclusive combination of kinetin and Zeatin improves the

consult your physician, Warmings: Avoid geltling product hito syes. For external use only. Keep out of reads of daildren. It infalloncocus, weet product foll discinctions are mentioned. Directions: Remove cap and gently press on the disc within the jer to release a measured amount of cream. Message 1 pump of Advanced Might Repst over the face and neck, lise every evening as paid of a physician-directad sistin case regimen.

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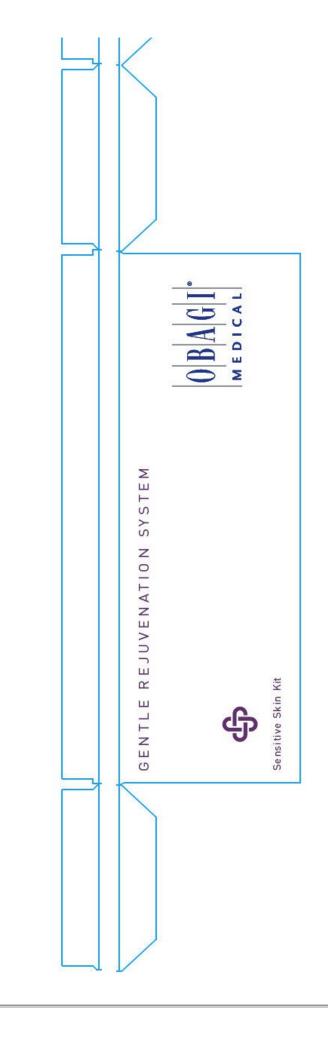
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# SYSTEM REJUVENATION **CENTLE**

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# GENTLE REJUVENATION SYSTEM

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone kit

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62032-525

# **Packaging**

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:62032-525-91	1 in 1 CARTON; Type 0: Not a Combination Product	11/04/2013	

# **Quantity of Parts**

~ =====		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	48 g

# Part 1 of 1

# GENTLE REJUVENATION FORTIFIED SUNSCREEN BROAD SPECTRUM SPF 30 WITH VITAMIN C

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream

# **Product Information**

Item Code (Source)	NDC:62032-130
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g
OCTISALATE (UNII: 4X49 Y0 59 6 W) (OCTISALATE - UNII:4X49 Y0 59 6 W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	27.9 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
ASCORBIC ACID (UNII: PQ6 CK8 PD0 R)		
CITRUS MAXIMA FRUIT RIND (UNII: 5NX3G75CA6)		
DIMETHICO NE 100 (UNII: RO266O364U)		
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:62032-130-70	48 g in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Info</b>	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/0 4/20 13	

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OTC monograph final	part352	11/0 4/20 13	

**Labeler** - Obagi Medical Products, Inc., a division of Valeant Pharmaceutcals North America LLC. (790553353)

Establishment			
Name	Address	ID/FEI	Business Operations
LABORATOIRE DR RENAUD INC.		202501565	MANUFACTURE(62032-525), LABEL(62032-525), PACK(62032-525)

Establishment			
Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-525), LABEL(62032-525), PACK(62032-525)

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