

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

**Obagi Medical Products, Inc., a division of Valeant Pharmaceuticals 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***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
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

Sensitive Skin Kit



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GENTLE REJUVENATION SYSTEM

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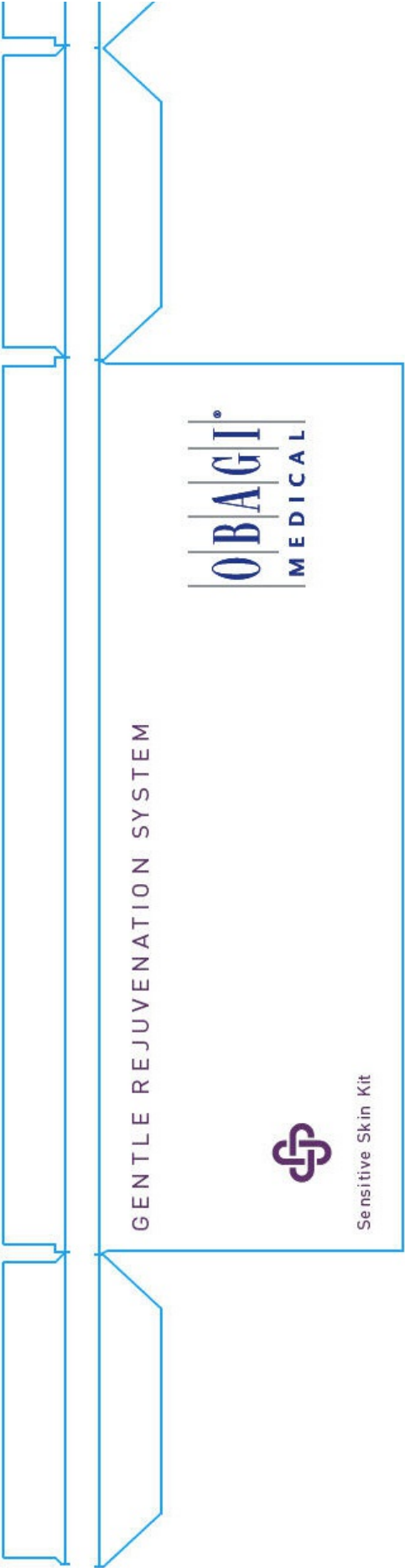
Sensitive Skin Kit



Les produits OBAGI sont distribués en France par OBAGI Medical, 10 rue de la République, 92100 Nanterre. Les prix sont indiqués hors taxes. Les prix TTC sont indiqués entre parenthèses.

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GENTLE REJUVENATION SYSTEM



Sensitive Skin Kit

OBAGI<sup>®</sup>  
MEDICAL

# GENTLE REJUVENATION SYSTEM

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone kit

## Product Information

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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
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Route of Administration	TOPICAL
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## 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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.9 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRUS MAXIMA FRUIT RIND (UNII: 5NX3G75CA6)	
DIMETHICONE 100 (UNII: RO266O364U)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

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

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/04/2013	

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OTC monograph final	part352	11/04/2013	

**Labeler** - Obagi Medical Products, Inc., a division of Valeant Pharmaceuticals 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)

Revised: 12/2017

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