

SALLY HANSEN OUCH-RELIEF WAX STRIP KIT- benzocaine
Coty US 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.

Drug Facts

(Benzocaine Wipes)

Active ingredient

6% Benzocaine

Purpose

Topical Analgesic

Uses

for temporary relief of pain and itching associated with minor skin irritations due to hair removal

Warnings

Allergy Alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

For external use only. Not intended for use by children under 13 years of age

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

Do not use

- over raw surfaces, or blistered areas

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Rub well (see enclosed instructions)

Use wipes no more than 3 to 4 times daily. Discard wipe after use

Adults and children 13 years of age and older apply to the area to be treated 10 minutes before hair removal

Children under 13 years of age consult a doctor

Other information

As with all products containing benzocaine, localized allergic reactions may occur after prolonged or repeated use

Inactive ingredients

ALCOHOL DENAT., AQUA/WATER/EAU, PROPYLENE GLYCOL, METHYLPARABEN

Questions or comments?

Call us at 1-800-953-5080 9:00AM - 5:00PM EST

Principal Display Panel - Sally Hansen Ouch-Relief Wax Strip Kit Label

OUCH-RELIEF™ WAX STRIP KIT

WAX

PAIN-
RELIEF
TECHNOLOGY™

Sally Hansen ®

FOR FACE & BIKINI

Pre-Treatment
for Pain-Free
Hair Removal

Results Last
Up to
8 Weeks!*

Ready &
Easy to Use

*Individual hair
re-growth results
may vary

Contouring Strip

SALLY HANSEN OUCH-RELIEF WAX STRIP KIT

benzocaine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-162
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-162-01	1 in 1 CARTON; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 APPLICATOR	3
Part 2	1 JAR	14.17 g
Part 3	2 PACKET	24

Part 1 of 3

OUCH-RELIEF NUMBING WIPE

benzocaine cloth

Product Information

Item Code (Source)	NDC:66184-163
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-163-01	3 in 1 PACKET		
1		1 in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/18/2018	

Part 2 of 3

AZULENE FINISHING OIL INGREDIENTS

other skin care preparations oil

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
INGR	SESAME OIL (UNII: QX10HYY4QV)	
INGR	C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	GUAIAZULENE (UNII: 2OZ1K9JKQC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14.17 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Cosmetic	10/18/2018
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Part 3 of 3

WAX STRIP

other skin care preparations strip

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ROSIN (UNII: 88S87KL877)	
INGR	GLYCERYL ROSINATE (UNII: SD112V492J)	
INGR	MINERAL OIL (UNII: T5L8T28FGP)	
INGR	HIGH DENSITY POLYETHYLENE (UNII: UG00KM4VR7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		12 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		10/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/18/2018	

Labeler - Coty US LLC (039056361)