SALLY HANSEN OUCH-RELIEF WAX KIT- benzocaine Coty US LLC

Drug Facts

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 raws 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 – Kit Label

New

OUCH-RELIEF™ WAX KIT

PAIN-RELIEF TECHNOLOGY

FOR FACE AND BODY

Pre-Treatment Helps Reduce Pain while Waxing

Results Last Up to 8 Weeks!*

Simply Rinses Off with Water

*Individual hair re-growth results may vary

Wax Net wt. 6.7 oz 189.9 g, 5 Benzocaine wipes, 20 Strips, 1 Spatula for face and body, Instructions

Dermatologist & Salon Tested



SALLY HANSEN OUCH-RELIEF WAX KIT

benzocaine kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66184-153

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-153-01	1 in 1 CARTON	01/01/2012	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	5
Part 2	1 JAR	189.9 g

Part 1 of 2

OUCH-RELIEF

benzocaine cloth

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.0543 g

Inactive Ingredients

Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
WATER (UNII: 059QF0KO0R)		
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
METHYLPARABEN (UNII: A2I8C7HI9T)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M017	01/01/2012	

Part 2 of 2

OUCH RELIEF WAX KIT

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Product Information

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Ingredient Kind	Ingredient Name	Quantity	

INGR	FRUCTOSE (UNII: 6YSS42VSEV)
INGR	DEXTROSE (UNII: IY9XDZ 35W2)
INGR	INVERT SUGAR (UNII: ED959S6ACY)
INGR	SUCROSE (UNII: C151H8M554)
INGR	WATER (UNII: 059QF0KO0R)
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)
INGR	GLYCERIN (UNII: PDC6A3C0OX)
INGR	MICA (UNII: V8A1AW0880)
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
INGR	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
INGR	HONEY (UNII: Y9H1V576FH)
INGR	ACETIC ACID (UNII: Q40Q9N063P)
INGR	COUMARIN (UNII: A4VZ22K1WT)
INGR	TOCOPHEROL (UNII: R0ZB2556P8)

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		189.9 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	
Cosmetic 01/01/2012				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	01/01/2012		

Labeler - Coty US LLC (039056361)

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