

SALLY HANSEN ZERO BUMP BIKINI- pramoxine hydrochloride spray
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.

zero bumps bikini spray

Drug Facts

Active Ingredient	Purpose
Pamoxine Hcl 1%	Topical Analgesic

Purpose

Topical Analgesic

Stop use and ask a doctor if

- Condition gets worse
- symptoms persist for more than 7 days
- symptoms clear up and occur again with a few days

Warnings

- For external use only
- When using this product avoid contact with the eyes

Keep out of reach of children

If swallowed, get medical help or contact a poison control center right away.

Directions

- Adults and children 2 years of age and older apply product to affected area not more than 3 to 4 times daily.
- Children under 2 years of age consult a doctor
- Use after shaving, waxing or after using hair removal creams. Will not stain lingerie, swimwear or clothing.

Inactive ingredients

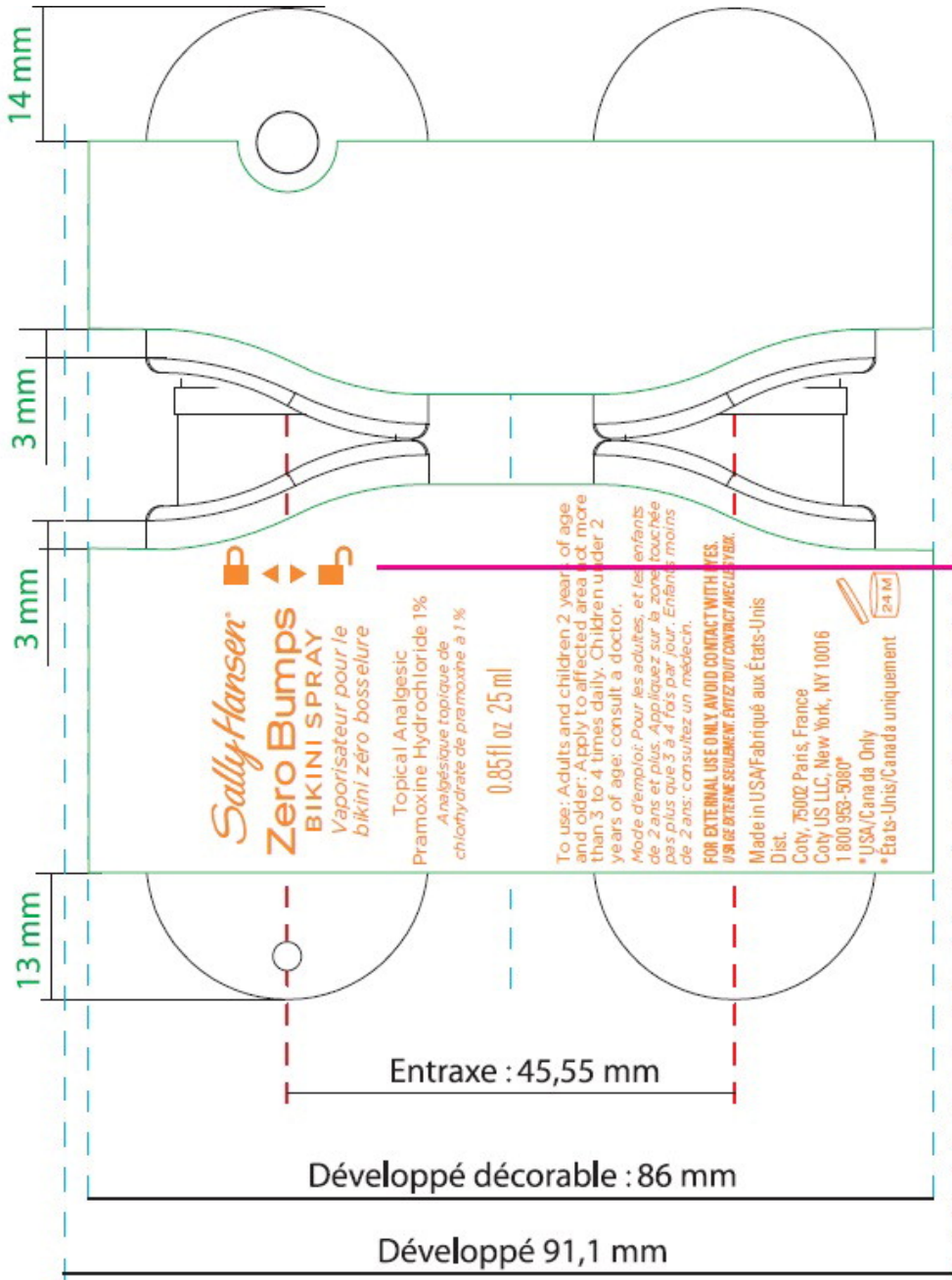
AQUA/WATER/EAU, HAMAMELIS VIRGINIANA (WITCH HAZEL) WATER,
ALCOHOL, GLYCERIN, BUTYLENE GLYCOL, SODIUM CITRATE, PHENOXYETHANOL,
LACTIC ACID,

PARFUM/FRAGRANCE, PEG-12 DIMETHICONE, ETHYLHEXYLGLYCERIN, TETRASODIUM EDTA, BENZYL BENZOATE, PROPYLENE GLYCOL, CITRUS AURANTIUM DULCIS (ORANGE) FLOWER EXTRACT, ORCHIS MASCULA FLOWER EXTRACT, PASSIFLORA INCARNATA EXTRACT, ALOE BARBADENSIS LEAF EXTRACT, SODIUM HYDROXIDE, GLYCINE SOJA (SOYBEAN) SEED EXTRACT, TOCOPHEROL, IMIDAZOLIDINYL UREA, METHYLPARABEN, DIAZOLIDINYL UREA, PROPYLPARABEN, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, CITRIC ACID

Uses

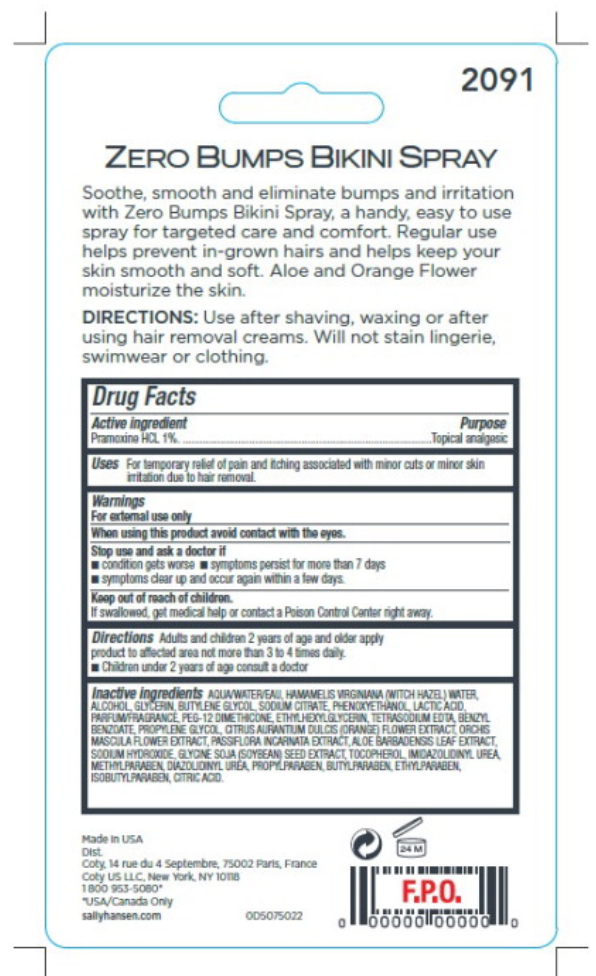
For temporary relief of pain and itching associated with minor cuts or minor skin irritation due to hair removal.

Label



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UPC - 074170364866

SALLY HANSEN ZERO BUMP BIKINI

pramoxine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-160
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HAMAMELIS VIRGINIANA FLOWER WATER (UNII: 222MYC9QUV)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	

BENZYL BENZOATE (UNII: N863NB338G)
CITRUS AURANTIUM FLOWER (UNII: O730ZX2Z83)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ORCHIS MASCULA FLOWER (UNII: 6H1JQK35LA)
PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
N-(3,4-BIS(HYDROXYMETHYL)-2,5-DIOXO-4-IMIDAZOLIDINYL)-N,N'-BIS(HYDROXYMETHYL)UREA (UNII: 483JN0JNJA)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LACTIC ACID, DL- (UNII: 3B8D35Y7S4)
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)
SOYBEAN OIL (UNII: 241ATL177A)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
.BETA.-TOCOPHEROL (UNII: 9U6A490501)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
BUTYLPARABEN (UNII: 3QPI1U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
CITRIC ACID ACETATE (UNII: DSO12WL7AU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-160-02	1 in 1 BLISTER PACK	01/01/2015	
1	NDC:66184-160-01	25 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2015	

Labeler - Coty US LLC (039056361)