

SALONPAS LIDOCAINE PLUS- benzyl alcohol, lidocaine hydrochloride cream
Hisamitsu America, Inc.

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.

Active ingredients

Benzyl alcohol 10%

Lidocaine HCl 4%

Purpose

Topical anesthetic

Uses

For temporary relief of pain

Warnings

For external use only

Do not use

- on wounds or damaged skin
- in large quantities
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

Adults and children 12 years of age and over:

- clean and dry affected area

- apply to affected area not more than 3 to 4 times daily

Children under 12 years of age:

consult a doctor

Other information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture
- Store with lid closed tightly

Inactive ingredients

aloe barbadensis leaf juice, aminomethyl propanol, butylene glycol, carbomer copolymer, cetearyl alcohol, ceteth phosphate, dicetyl phosphate, dimethicone, glyceryl monostearate, hydroxyl acrylate/sodium acryloyldimethyl taurate copolymer, polysorbate, SD alcohol 40-B, squalane, steareth, water

Questions or comments?

Toll free **1-800-826-8861** www.salonpas.us

Principal Display Panel

Hisamitsu

NDC#55328-902-03

Non-Greasy Cream

Salonpas LIDOCAINE PLUS Pain Relieving Cream

TOPICAL ANALGESIC

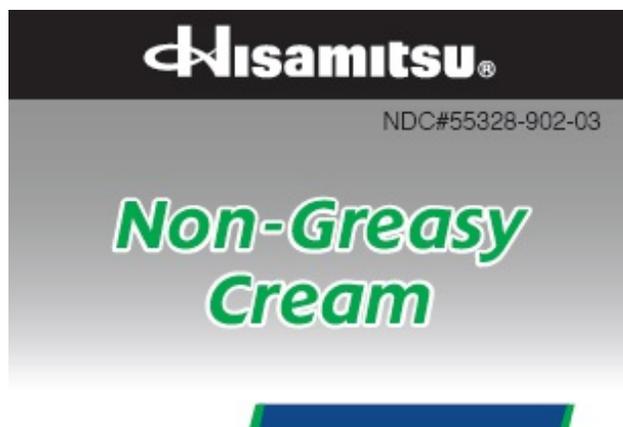
4% LIDOCAINE MAXIMUM STRENGTH*1

plus 10% Benzyl alcohol

- 2 Powerful Anesthetics
- Fast Acting
- Numbing Relief
- Unscented

MADE IN USA

3 OZ (85 g)



LIDOCAINE PLUS
Pain Relieving Cream

Salonpas®

TOPICAL ANALGESIC

**4% LIDOCAINE
MAXIMUM STRENGTH^{††}**

+10% Benzyl alcohol

- **2 Powerful Anesthetics**
 - *Fast Acting*
 - *Numbing Relief*
 - *Unscented*

MADE IN USA

3 OZ (85 g)

SALONPAS LIDOCAINE PLUS

benzyl alcohol, lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55328-902
Route of Administration	TOPICAL, PERCUTANEOUS, TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10.0000 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4.0000 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
alcohol (UNII: 3K9958V90M)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
SQUALANE (UNII: GW89575KF9)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55328-902-03	1 in 1 BOX	06/23/2017	
1		85 g in 1 TUBE; 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	06/23/2017	

Labeler - Hisamitsu America, Inc. (191877802)

Revised: 11/2018

Hisamitsu America, Inc.