

ASTONEA BURN CREAM- lidocaine cream
ASTONEA LABS PRIVATE LIMITED

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.

ASTONEA Burn Cream

Active Ingredients

Lidocaine HCL 0.5% Topical Analgesic

Benzalkonium Chloride 0.13% Topical Antiseptic

Purpose

Topical Analgesic

Topical Antiseptic

Uses

For temporary relief of pain and itching associated with:

- Sunburn
- Minor burns,
- Insect bites,
- Minor skin irritation,
- Cuts
- Scrapes

Warnings

FOR EXTERNAL USE ONLY

Do Not Use

Do Not Use:

- In the eyes
- Over large areas of the body or on deep puncture wounds, animal bites or serious burns.
- In large quantities, particularly over raw surfaces or blistered areas.

Stop Use

- the condition gets worse
- condition clears up and recurs within a few days
- condition persists for more than 7 days

If pregnant or breast feeding

ask a health care 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 2 years and over:**

- clean the affected area
- apply a small amount of this product on the area 3 or 4 times daily.
- may be covered with a sterile bandage

Children under 2 years

- consult a doctor

Other Information

•store in a cool, dry area 59°-86°F (15°-30°C) •tamper evident sealed packets do not use any opened or torn packets

Inactive ingredients

Aloe barbadensis leaf juice, Cetearyl alcohol, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl stearate/PEG-100 stearate, Maltodextrin, Mineral oil, Phenoxyethanol, Propylene glycol, Purified water, Stearic acid, Triethanolamine.

Principal Display Panel



ASTONEA BURN CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII: 98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PHENOXYETHANOL (UNII: HIE492Z33T)	
GLYCERIN (UNII: PDC6A3COOX)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-100-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/16/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/16/2023	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

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