

LIDOCAINE PAIN RELIEF- lidocaine hcl cream
ASTONEA LABS PRIVATE LIMITED

ASTONEA LIDOCAINE 4 % CREAM

Active ingredients

Lidocaine HCl 4%

Purpose

Lidocaine HCl - Topical anesthetic

Uses

temporarily relieves minor pain

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed
- do not get into eyes
- do not bandage tightly or apply external heat (such as a heating pad) to the area of use

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness, rash, or irritation occurs

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center (800-222-1222) right away.

Directions

- adults and children 12 years and over: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
- children under 12 years: ask a doctor

Inactive ingredients

aloe vera leaf, carbomer 940, ceteth-20, cetostearyl alcohol, dimethicone, glycerin, glyceryl monostearate, isopropyl alcohol, petrolatum, phenoxyethanol, polysorbate 60, trolamine, water

Package/Label Principal Display Panel

ASTONEA

**Lidocaine
Pain Relief
Cream**

Lidocaine 4% / Topical Anesthetic

Provides Fast,
Penetrating Pain Relief
Desensitizes Aggravated Nerves
Unscented Formula

2.7 OZ (76.5g)

Drug Facts	
Active ingredient	Purpose
Lidocaine HCl 4%	Topical anesthetic
Uses Temporarily relieves minor pain	
Warnings For external use only. Avoid contact with eyes.	
Do not use ■ on large areas of the body or on cut, irritated or swollen skin ■ on puncture wounds ■ for more than one week without consulting a doctor	
When using this product ■ use only as directed. Read and follow all directions and warnings on this carton ■ do not allow contact with the eyes ■ do not bandage or apply local heat (such as heating pads) to the area of use	
Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days or 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 and pets. If swallowed, get medical help or contact Poison Control Center (800-222-1222) right away.	
Directions ■ adults and children over 12 years: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period. Children 12 years or younger: ask a doctor	
Other Information ■ Store at room temperature	
Inactive ingredients aloe vera leaf, carbomer 940, ceteth-20, cetostearyl alcohol, dimethicone, glycerin, glyceryl monostearate, isopropyl alcohol, petrolatum, phenoxyethanol, polysorbate 60, trolamine, water	

Child-Resistant Packaging

Manufactured by:
Astonea Labs Private Limited
Village Haripur, Tehsil Raipurani,
Near Mouli Police Station, Panchkula,
Haryana, India - 134204

Made in India

LIDOCAINE PAIN RELIEF

lidocaine hcl cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77338-009

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-009-04	76.5 g in 1 TUBE; Type 0: Not a Combination Product	03/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/12/2024	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 3/2024

ASTONEA LABS PRIVATE LIMITED