

THERACARE 4% LIDOCAINE CREAM- lidocaine hydrochloride cream
Veridian Healthcare

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.

TheraCare 4% Lidocaine Cream

TheraCare 4% Lidocaine Cream. 2.7 oz

Drug Facts

Active ingredient

Lidocaine HCl 4%

Purpose

Lidocaine HCl
4%.....Topical
anesthetic

Use

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 warning 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.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

adults and children over 12 years:

■ apply a thin layer to the 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

Inactive ingredients

aloe vera leaf, carbopol 940, cetostearyl alcohol, dimethicone 350, edetate disodium, glycerin, glyceryl monostearate, isopropyl alcohol, phenoxyethanol, polysorbate 60, steareth 2, steareth 21, water

PRINCIPAL DISPLAY PANEL



THERACARE 4% LIDOCAINE CREAM

lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-933
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
STEARETH-2 (UNII: V56DFE46J5)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARETH-21 (UNII: 53J3F32P58)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-933-01	1 in 1 CARTON	12/01/2022	
1		76.5 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	12/01/2022	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
ANICARE PHARMACEUTICALS PRIVATE LIMITED		916837425	manufacture(71101-933)

