PAIN ITCH RELIEF- lidocaine hci cream
Trifecta Pharmaceutical USA 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.

Globe Maximum Strength Pain & Itch Relief Cream

DRUG FACTS

Active Ingredient

Lidocaine HCl 4%

Purpose

Topical Anesthetic

Uses

Temporarily relieves minor pain

Warnings

For external use only.

When using this product

Use only as directed.

Do not allow contact with eyes.

Do not bandage or apply local heat such as heating pads to the area of use

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

If Pregnant or Breast Feeding

Ask a health professional before 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.

Keep out of Reach of Children

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

Questions

For Questions please call 1 888 296 9067

Other Information

Store at room temperature

Inactive Ingredient:

Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl Sterate, Light Mineral Oil, Petrolatum, Polyoxyethylene Lauryl Ether, Purified Water, Sodium Lauryl Sulfate.

Distributed By

Trifecta Pharmaceuticals USA

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

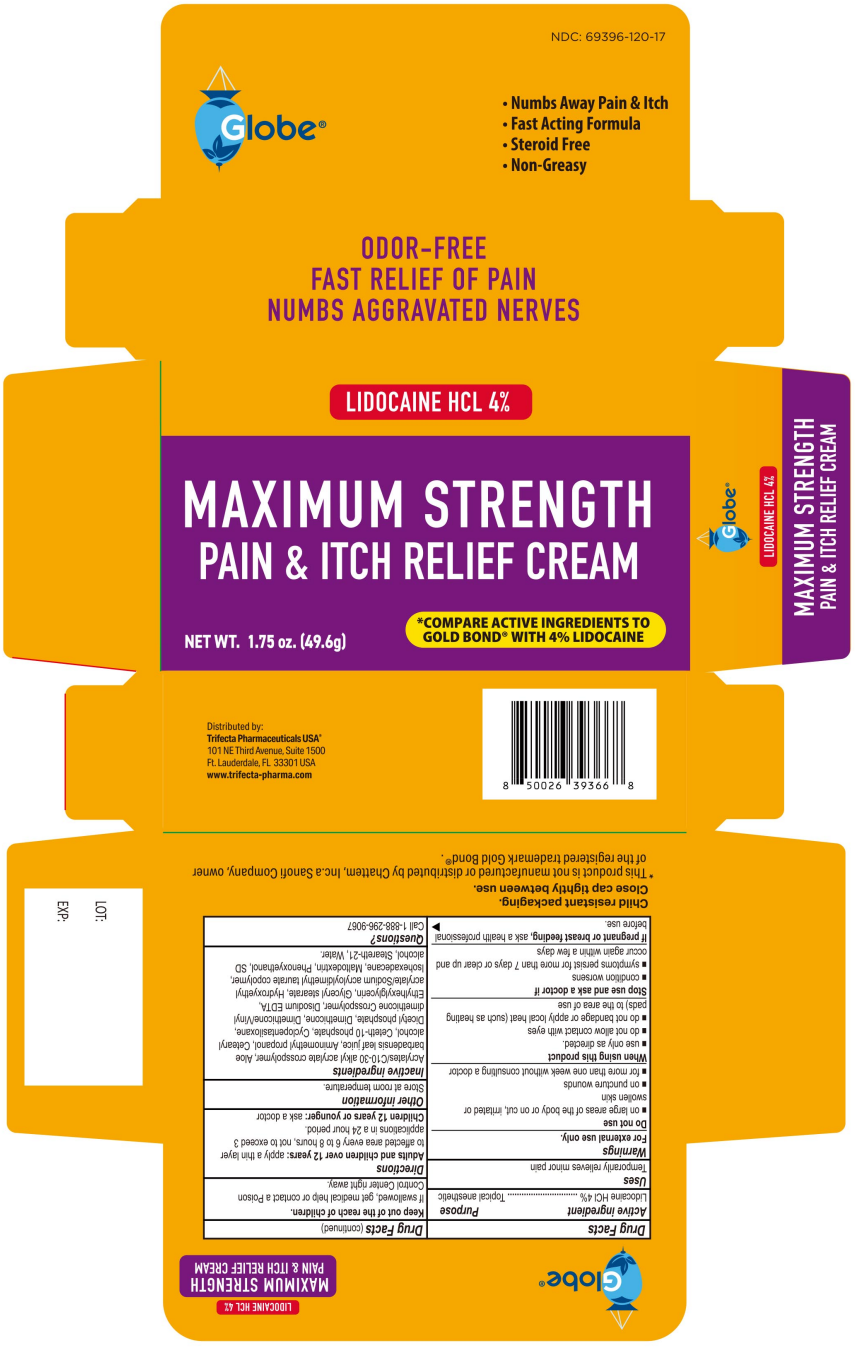
www.trifecta-pharma.com

This product is not manufactured or distributed by Chattem, Inc. a Sanofi Company owner of the registered trademark Gold Bond.

Packaging

OUTSIDE BOX

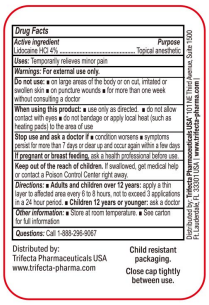
OUTSIDE BOX



INNER LABEL

Front

Back



PAIN ITCH RELIEF

lidocaine hci cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69396-120
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
STEARETH-21 (UNII: 53J3F32P58)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CYCLOMETHICONE 7 (UNII: KCK5L8VU47)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S	

AT 1.5%) (UNII: 86FQE96TZ4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-120-17	1 in 1 BOX	01/06/2023	
1		49.6 g in 1 BOTTLE; 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	01/06/2023	

Labeler - Trifecta Pharmaceutical USA LLC (079424163)

Revised: 2/2023 Trifecta Pharmaceutical USA LLC