SERUM X- lidocaine hydrochloride gel AO Biologix, 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.

Serum X Pain Relief Gel

Active ingredient

Lidocaine Hydrochloride 0.5%

Purpose

Lidocaine Hydrochloride 0.5%.....Topical Analgesic

Uses

For the temporary relief of pain

Warnings

For external use only

Do not use

• in large quantities, particularly over raw surfaces or blistered areas

When using this product

• avoid contact with the eyes

Stop use and ask doctor if

- condition worsens
- any allergic reaction occurs
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breastfeeding, ask a health professional before use.

Keep out of the reacho f children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

Children under 2 years of age: consult a doctor

Other information

- store in a cool, dry place away from light
- this package is child-resistant

Inactive ingredients

Water, Hydroxyethylcellulose, Disodium Phosphate, Sodium Phosphate, Methylparaben, Superoxide Dismutase, Propylparaben

Questions or comments?

Call 855-910-1252 Monday-Friday; 9am-5pm MST.

SerumX.com

AO Biologix

Serum X

Pain Relief Gel

Fast Acting Lidocaine

With Antioxidant Properties

30mL/1 Fl. oz.





SERUM X

lidocaine hydrochloride gel

v	roc	шст	Inform	NATION
		uct		Ialivii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82317-001

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

Inactive Ingredients			
Ingredient Name	Strength		
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)			

SODIUM PHOSPHATE (UNII: SE337SVY37)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
SUPEROXIDE DISMUTASE (SACCHAROMYCES CEREVISIAE) (UNII: W2T4YRA9AD)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:82317-001- 30	1 in 1 CARTON	04/21/2022		
1		30 g in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:82317-001- 01	1 in 1 PACKAGE	07/01/2022		
2		0.5 g in 1 PACKET; Type 0: Not a Combination Product			

	Marketing Information				
on Number or Monograph Citation	Marketing Start Date	Marketing End Date			
	04/21/2022				
	- -	Citation Date			

Labeler - AO Biologix, LLC (102188692)

Establishment				
Name	Address	ID/FEI	Business Operations	
TRI-PAC, INC.		020844956	manufacture(82317-001)	

Revised: 4/2022 AO Biologix, LLC