SANINTA 10% POVIDONE-IODINE- povidone-iodine solution liquid Lernapharm

Drug Facts - Saninta 10% w/v Povidone-Iodine Solution

Active Ingredient

Povidone-Iodine 10% w/v

Purpose

Antiseptic

Use

Antiseptic skin preparation. Helps reduce bacteria that potentially can cause skin infection.

Warnings

For external use only.

Do not use

Do not use

- if allergic to iodine
- in the eyes

Stop use and ask a doctor

Stop use and ask a doctorif

- injuries are deep puncture wounds or serious burns
- redness, irritation, swelling or pain persists or increases
- infection occurs

Avoid pooling beneath patient

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Keep out of reach of children

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

Directions

- Clean the area.
- apply locally as needed

Other Information

- 1% titratable iodine
- not made with natural rubber latex
- for hospital or professional use only
- Store at room temperature between 59-86°F (15 30°C).
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients

Citric Acid, Glycerol, Nonoxynol-9, Purified Water USP, Sodium Hydroxide, Sodium Phosphate Dibasic

Questions or Comments?

Questions or Comments? Tel.: 1-866-322-4634, weekdays between 8:00 am and 4:00 pm EST

Package Label - Principal Display Panel

NDC: 68356-601-01 / 68356-601-601-02 / 68356-601-03

Product # 601-01 / 601-02 / 601-03

Hold upright

[Tear here and pour]

[Three 4-inch antiseptic swabsticks impregnated with 10% W/V povidone-iodine solution]

[Tear open]

Saninta

Antiseptic Solution

10% w/v Povidone-Iodine Solution

10% Povidone-Iodine

[0.75 Fl. oz (22.5 mL)]

[0.5 Fl. oz (15 mL)]

Do Not Reuse

multiple-use cross-through logo

UPC Code

Manufactured by:

Lernapharm (LORIS) Inc.

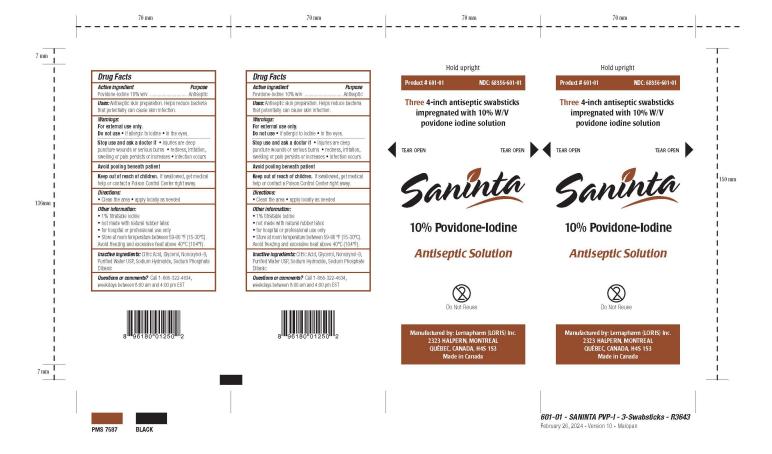
2323 HALPERN, MONTREAL

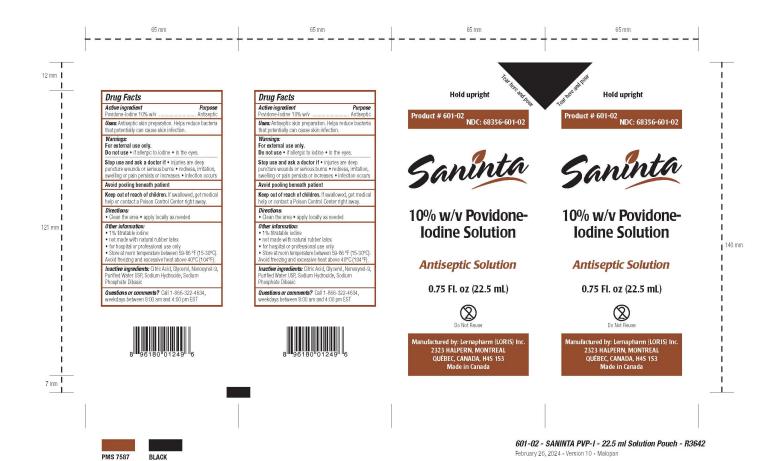
QUEBEC, CANADA H4S 1S3

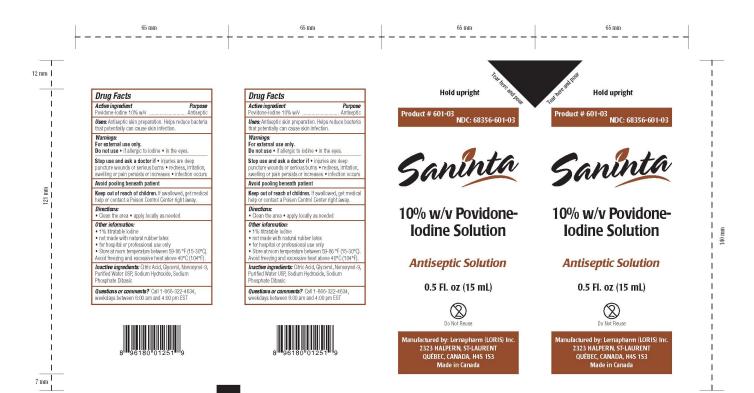
Made in Canada

LOT #: XXXX

EXP.: MM/YYYY







PMS 7587

601-03 - SANINTA PVP-I - 15 ml Solution Pouch - R3652

SANINTA 10% POVIDONE-IODINE

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68356-601

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) IODINE 100 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
NONOXYNOL-9 (UNII: 48Q180SH9T)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 9425516E2T)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:68356- 601-01	3 in 1 POUCH	02/26/2024			
1		2.3 mL in 1 APPLICATOR; Type 0: Not a Combination Product				
2	NDC:68356- 601-02	22.5 mL in 1 PACKET; Type 0: Not a Combination Product	02/26/2024			
3	NDC:68356- 601-03	15 mL in 1 PACKET; Type 0: Not a Combination Product	11/14/2024			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	505G(a)(3)	02/26/2024		

Labeler - Lernapharm (206940905)

Registrant - Lernapharm (206940905)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lernapharm		206940905	manufacture(68356-601), analysis(68356-601), label(68356-601), pack(68356-601)	

Revised: 11/2024 Lernapharm