SANINTA 10% POVIDONE-IODINE- povidone-iodine solution liquid
LL Pharma

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 59-86ºF (15 - 30ºC).
- Avoid freezing and excessive heat above 40ºC (104ºF).

Inactive ingredients

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

Questions or Comments?

Questions or Comments? Tel.: 1-833-336-6159

Package Label - Principal Display Panel

NDC: 81351-004-01 / 81351-004-02

Product # 004-01 / 004-02

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]

[0.75 Fl.ox (22.5 mL)]

Latex cross-through logo

multiple-use cross-through logo

UPC Code

Manufactured by:

LL Pharma Inc.

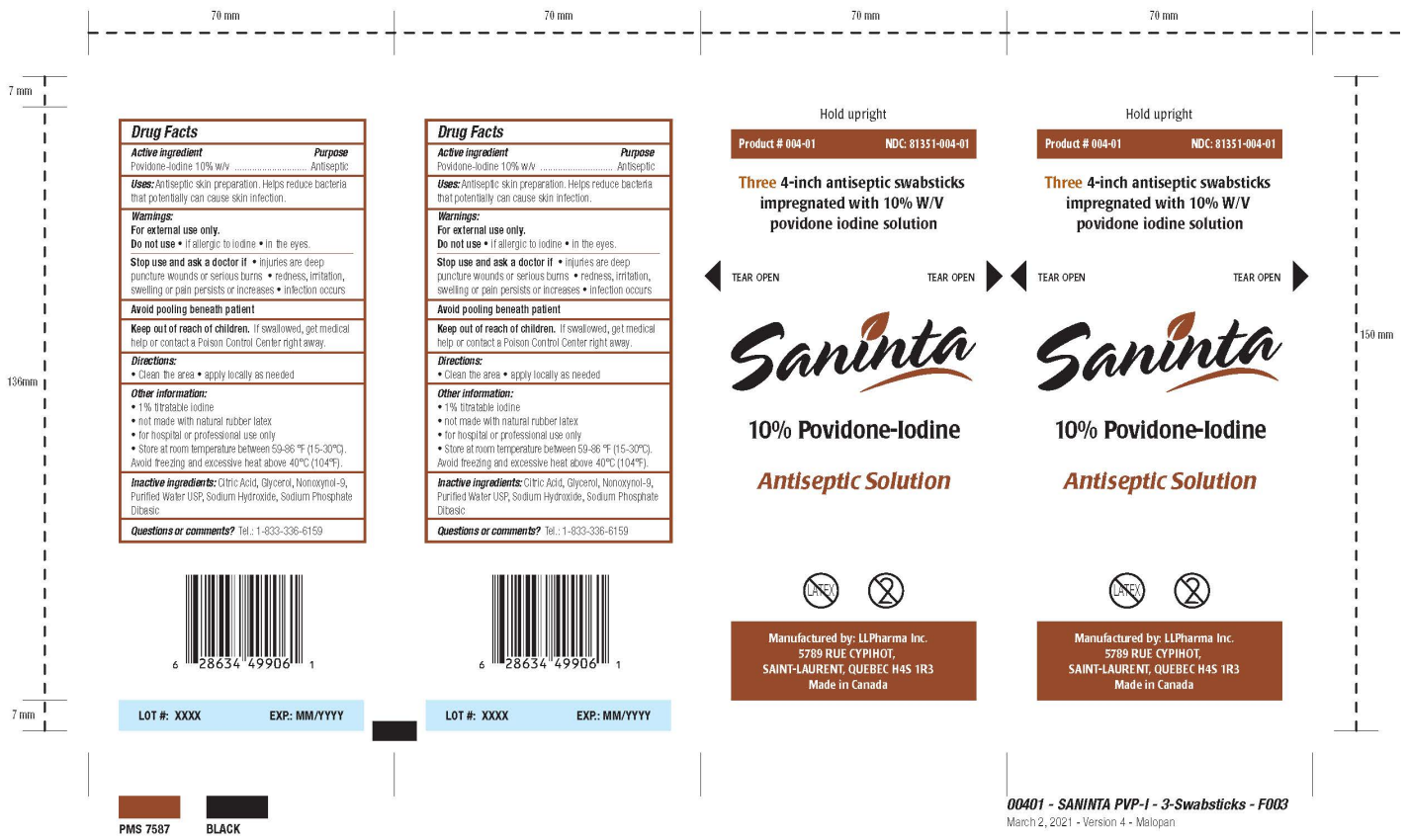
5789 rue Cypihot, Saint-Laurent, Quebec H4S 1R3

Made in Canada

www.llpharmainc.com

LOT #: XXXX

EXP.: MM/YYYY



PMS 7587 BLACK

00401 - SANINTA PVP-I - 3-Swabsticks - F003
March 2, 2021 - Version 4 - Malopan

PMS 7587 BLACK

00402 - SANINTA PVP-I - 22.5 ml Solution Pouch - F002
March 2, 2021 - Version 4 - Malopan

SANINTA 10% POVIDONE-IODINE

povidone-iodine solution liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81351-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**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: 94255I6E2T)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:81351-004-01	3 in 1 POUCH	08/25/2021	
1		2.3 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:81351-004-02	22.5 mL in 1 PACKET; Type 0: Not a Combination Product	08/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	08/25/2021	

Labeler - LL Pharma (206925146)

Registrant - LL Pharma (206925146)

Establishment

Name	Address	ID/FEI	Business Operations
LL Pharma		206925146	manufacture(81351-004) , analysis(81351-004) , label(81351-004) , pack(81351-

Inc.		206925146	004)