

**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 doctor if

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

Avoid pooling beneath patient

Avoid pooling beneath patient

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

65 mm	65 mm	65 mm	65 mm
12 mm			
121 mm			
7 mm			


Drug Facts	
Active ingredient Povidone-iodine 10% w/v	Purpose Antiseptic
Uses: Antiseptic skin preparation. Helps reduce bacteria that potentially can cause skin infection.	
Warnings: For external use only. Do not use • if allergic to iodine • in the eyes.	
Stop use and ask a doctor if • injuries are deep puncture wounds or serious burns • redness, irritation, swelling or pain persists or increases • infection occurs	
Avoid pooling beneath patient	
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, Nonoxonyl-9, Purified Water USP, Sodium Hydroxide, Sodium Phosphate Dibasic	
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8 96180 01249 6

Hold upright


Product # 601-02 NDC: 68356-601-02



10% w/v Povidone-Iodine Solution

Antiseptic Solution


0.75 Fl. oz (22.5 mL)

 Do Not Reuse

Manufactured by: Lernapharm (LORIS) Inc.
2323 HALPERN, MONTREAL
QUÉBEC, CANADA, H4S 1S3
Made in Canada

Hold upright


Product # 601-02 NDC: 68356-601-02



10% w/v Povidone-Iodine Solution

Antiseptic Solution

0.75 Fl. oz (22.5 mL)


 Do Not Reuse

Manufactured by: Lernapharm (LORIS) Inc.
2323 HALPERN, MONTREAL
QUÉBEC, CANADA, H4S 1S3
Made in Canada

601-02 - SANINTA PVP-I - 22.5 ml Solution Pouch - R3642
February 26, 2024 - Version 10 - Malopan

65 mm	65 mm	65 mm	65 mm
12 mm			
121 mm			
7 mm			


Drug Facts	
Active ingredient Povidone-iodine 10% w/v	Purpose Antiseptic
Uses: Antiseptic skin preparation. Helps reduce bacteria that potentially can cause skin infection.	
Warnings: For external use only. Do not use • if allergic to iodine • in the eyes.	
Stop use and ask a doctor if • injuries are deep puncture wounds or serious burns • redness, irritation, swelling or pain persists or increases • infection occurs	
Avoid pooling beneath patient	
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, Nonoxonyl-9, Purified Water USP, Sodium Hydroxide, Sodium Phosphate Dibasic	
Questions or comments? Call 1-866-322-4634, weekdays between 8:00 am and 4:00 pm EST.	



8 96180 01251 9

Hold upright


Product # 601-03 NDC: 68356-601-03



10% w/v Povidone-Iodine Solution

Antiseptic Solution


0.5 Fl. oz (15 mL)

 Do Not Reuse

Manufactured by: Lernapharm (LORIS) Inc.
2323 HALPERN, ST-LAURENT
QUÉBEC, CANADA, H4S 1S3
Made in Canada

Hold upright


Product # 601-03 NDC: 68356-601-03



10% w/v Povidone-Iodine Solution

Antiseptic Solution

0.5 Fl. oz (15 mL)

 Do Not Reuse

Manufactured by: Lernapharm (LORIS) Inc.
2323 HALPERN, ST-LAURENT
QUÉBEC, CANADA, H4S 1S3
Made in Canada

601-03 - SANINTA PVP-I - 15 ml Solution Pouch - R3652
November 05, 2024 - Version 02 - Malopan Communications

SANINTA 10% POVIDONE-IODINE

povidone-iodine solution liquid

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	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: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)

