

TM TITUS MEDICAL ANTISEPTIC NON STERILE- povidone-iodine solution
Titus Medical LLC

81526-001

Active Ingredient:

Povidone-Iodine USP (10%)

Purpose

Antiseptic

Use:

Antiseptic skin preparation

Warnings:

Do not use if allergic to iodine in eyes

For external use only

Avoid "pooling" beneath patients.

Avoid excessive heat. Store at room temperature.

Ask a doctor before use if injuries are deep or puncture wounds, or serious burns

Stop use and ask a doctor if

- redness, irritation, swelling, or pain persists or increases
- infection occurs

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately

Apply locally as need

Other information

- 1% titratable iodine
- not made with natural rubber latex
- for hospital or professional use only

Inactive Ingredient

Citric acid, Disodium phosphate, Nonoxynol-9, Sodium hydroxide, Water

LOT



Drug Facts (continued)

Warnings

Ask a doctor before use if injuries are
Deep or puncture wounds, or serious burns

Stop use and ask doctor if

redness, irritation, swelling, or pain persists or
increases
infection occurs

Avoid pooling beneath patient

Avoid excessive heat. Store at room
temperature.

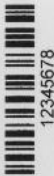
Keep out of reach of children. In case of
accidental ingestion, seek professional
assistance or consult a poison control center
immediately.

Directions apply locally as needed

Other information

1% titratable iodine
not made with natural rubber latex
for hospital or professional use only

Inactive ingredients citric acid, disodium
phosphate, nonoxynol-9, sodium hydroxide,
water



For questions, comments, or
to report serious side effects:
888-550-6185
Monday-Friday
10:00am-4:30pm EST
Titus Medical LLC, Fort Mill,
SC 29715 USA
www.titusmed.com

NDC 55555-5555-5



TITUS MEDICAL

ONE FLUID OUNCE
POVIDONE-IODINE
SOLUTION

ANTISEPTIC
Non-Sterile Solution

1 Fl. oz. (30mL)

Drug Facts

Active ingredient	Purpose
Povidone-iodine USP 10%.....	Antiseptic

USE antiseptic skin preparation

Warnings

Do not use if allergic to iodine in eyes
For external use only



Reorder No. PI-1011

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81526-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81526-001-01	30 mL in 1 POUCH; Type 0: Not a Combination Product	02/04/2021	
2	NDC:81526-001-02	200 in 1 BOX	02/04/2021	
2		30 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	02/04/2021	

Labeler - Titus Medical LLC (080306309)

Registrant - Titus Medical LLC (080306309)

Establishment

Name	Address	ID/FEI	Business Operations
Lights Medical Manufacture Co., Ltd.		529128649	manufacture(81526-001)

