

POVIDONE-IODINE SOLUTION- povidone-iodine solution
Tongzhou Ruihong Medical Products Factory

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.

Drug Fact

Active Ingredient

POVIDONE-IODINE USP 10%

Purpose

Antiseptic

Warnings

Do not use if allergic to iodine.

For External use only.

Ask a doctor before use if injuries are

--Deep or puncture wounds

--serious burns

stop use ask a doctor if

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

--infection occurs

Do not use in eyes

Avoid "pooling" beneath patient. Prolonged exposure to wet solution may cause skin irritation.

Keep out of reach of children.

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 --latex free ---for hospital or professional use only

Use

Antiseptic skin preparation

Inactive Ingredients

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, Water

POVIDONE-IODINE SOLUTION

4 Fl.Oz.(118ml)

Drug Facts	
Active ingredient	Purpose
Povidone-iodine USP 10%	Antiseptic
Use antiseptic skin preparation	
Warnings	
Do not use if allergic to iodine	
For external use only	
Ask a doctor before use if injuries are	
■ Deep or puncture wounds ■ serious burns	
Stop use ask a doctor if	
■ Renss,irritation,swelling or pain persists or increases	
■ Infection occurs	
continued	

Drug Facts,cont.
Do not ues in eyes
Avoid "pooling"benesth patient. Prolonged exposure to wet solution may cause skin irritation.
Keep out of reach of children. In case of axcidental ingestion,seek professional assistance or consult a poison control center immediately.
Directions
apply locally as needed
Other information
■ 1%titrarabil iodine ■ latex free
■ For hospital or professional use only
Inactive ingredients
citric acid,disodium phosphate, nonoxynol-9,sodium hydroxide,water

POVIDONE-IODINE SOLUTION

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58488-006
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	0.01 mg in 1 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58488-006-01	1201 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part333C	05/20/2014	
---------------------	----------	------------	--

Labeler - Tongzhou Ruihong Medical Products Factory (421312726)

Establishment

Name	Address	ID/FEI	Business Operations
Tongzhou Ruihong Medical Products Factory		421312726	manufacture(58488-006)

Revised: 5/2014

Tongzhou Ruihong Medical Products Factory