

JIANZE POVIDONE-IODINE - povidone-iodine gel
Changzhou Jianze Sanitary Material Co., Ltd.

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.

JIANZE POVIDONE-IODINE GEL SWABSTICK

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ACTIVE INGREDIENT

Povidone-Iodine USP 10%

PURPOSE

Antiseptic

USE:

Antiseptic skin preparation

WARNINGS:

Do not use if allergic to Iodine.

STOP USE AND ASK A DOCTOR IF:

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

KEEP OUT OF REACH OF CHILDREN.

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

For External Use Only.

DIRECTIONS

Apply locally as needed.

OTHER INFORMATION

- 1% titratable iodine
- latex free

INACTIVE INGREDIENTS:

Disodium phosphate, glycerin, hydroxyethylcellulose, nonoxynol-10, dimethicone, water.

JIANZE POVIDONE-IODINE GEL SWABSTICK 1 COUNT (50666-005-01)



Lot:JZ31512
Exp:03/14
600-0401

Hold Upright and Tear Here

**Povidone-Iodine
Gel Swabstick**

**4" (10.2 cm)
Saturated Swabstick**



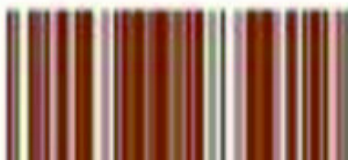
Sterile



**Sterility guaranteed unless
opened or damaged.**

Manufactured by:
Changzhou Jianze Sanitary Material Co., Ltd
Changzhou City, Jiangsu, China

Made in China



DRUG FACTS:

Active Ingredient
Povidone-Iodine USP 10%

Purpose
Antiseptic

Hold Upright and Tear

Use: antiseptic skin
preparation

Warnings: Do not use if
allergic to iodine

Stop use and ask a doctor if

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

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

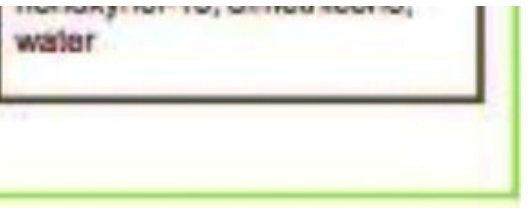
For external use only.

Directions: Apply locally as
needed

Other information:

- 1% titratable iodine
- latex free

Inactive Ingredients:
Disodium phosphate, glycerin,
hydroxyethylcellulose,
nonoxonyl-10, dimethicone.



JIANZE POVIDONE-IODINE

povidone-iodine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50666-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (POVIDONE-IODINE - UNII:85H0HZU99M)	POVIDONE-IODINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-10 (UNII: K7O76887AP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50666-005-01	2.1 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333E	06/14/2012	

Labeler - Changzhou Jianze Sanitary Material Co., Ltd. (421279569)

Registrant - Changzhou Jianze Sanitary Material Co., Ltd. (421279569)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Jianze Sanitary Material Co., Ltd.		421279569	manufacture

Revised: 6/2012

Changzhou Jianze Sanitary Material Co., Ltd.