

POVIDONE-IODINE PAINT SOLUTION- povidone-iodine solution
Changzhou Maokang Medical Products 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.

Povidone-Iodine Paint Solution

MK Povidone-Iodine Paint Solution

Active Ingredient

Povidone-Iodine 10%

Purpose

Antiseptic

Use

Antiseptic skin preparation

Warnings

Do not use

- if allergic to Iodine
- in the eyes

Stop use and ask 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.

Avoid pooling beneath the patient

Ask a doctor before use if injuries are

- deep puncture wounds
- serious burns

Directions

apply locally as needed

Other Information

- 1% titratable
- for hospital or professional use only

Inactive Ingredients

alkyl glucoside, anhydrous citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide, sodium hydroxide, purified water


MK Povidone-Iodine Paint Solution

 **497C**


 **BLACK**

11cm

6.5cm



MaoKang Medical



**Povidone-Iodine
Paint Solution**

NDC:59050-551-44
Reorder:110802006
Antiseptic Non-Sterile solution

NOT MADE WITH
natural rubber latex

Non Sterile

4 Fl.OZ.(118ml)

Drug Facts		Drug Facts(continued)
<p>Active ingredient Purpose Povidone-Iodine 10%w/w.....Antiseptic</p> <p>Use for antiseptic skin preparation</p> <p>Warnings</p> <ul style="list-style-type: none"> ■ do not use if allergic to iodine ■ do not use in the eye <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ redness,irritation,swelling or pain persists or increases ■ infection occurs <p>Keep out of reach of children. In case of accidental ingestion,seek professional assistance or consult a Poison Control Center immediately.</p> <p>Avoid pooling beneath patient.</p>	<p>Other information</p> <ul style="list-style-type: none"> ■ 1% titratable iodine ■ for hospital or professional use only <p>Inactive ingredients: Alkyl glucoside, Anhydrous citric acid, Glycerin, Hydroxyethyl cellulose, Nonoxynol-10, Potassium iodide, Sodium hydroxide, Purified water</p> <p>Manufactured by Changzhou Maokang Medical Products Co.,Ltd Add:No.9-P,The North of Danyangmen Road,Jintan District, Changzhou,Jiangsu Province,China.PC.:213200 Tel:+86-519-80186516; Fax:+86-519-80186502 Made in China</p>	
<p>Directions</p> <ul style="list-style-type: none"> ■ apply locally as needed 	<p>LOT: EXP:</p>	

POVIDONE-IODINE PAINT SOLUTION

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59050-551
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0 HZU99M) (IODINE - UNII:9679 TC07X4)	IODINE	11 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)	
NONOXYNOL-10 (UNII: K7O76887AP)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POTASSIUM IODIDE (UNII: 1C4QK22F9J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59050-551-44	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
2	NDC:59050-551-42	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/10/2020	

Labeler - Changzhou Maokang Medical Products Co.,Ltd (421317073)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical Products Co.,Ltd		421317073	manufacture(59050-551)

Revised: 6/2020

Changzhou Maokang Medical Products Co.,Ltd