# POVIDONE-IODINE GEL SOLUTION- povidone-iodine solution Changzhou Moakang 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.

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#### **Povidone-Iodine Gel Solution**

#### MK Povidone-Iodine Gel 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**

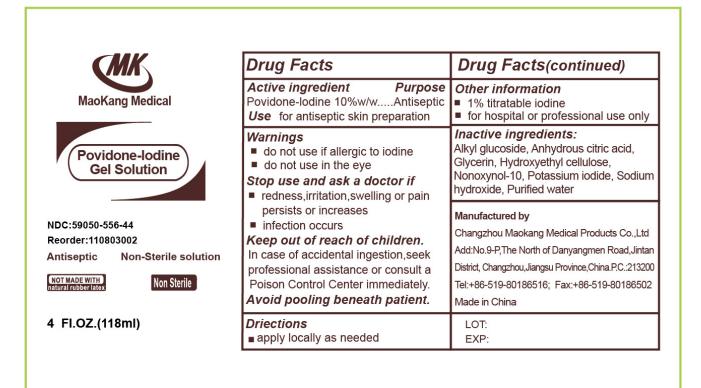
alkyl glucoside, anhydrous citric acid, glycerin, hydroxyethyl cellulose, nonoxynol-10, potassium iodide, sodium hydroxide, purified water

#### MK Povidone-Iodine Gel Solution





## 11cm



## POVIDONE-IODINE GEL SOLUTION

povidone-iodine solution

| <b>Product Information</b> |                |                    |               |
|----------------------------|----------------|--------------------|---------------|
| Product Type               | HUMAN OTC DRUG | Item Code (Source) | NDC:59050-556 |
| Route of Administration    | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                                      |                   |               |
|--|-------------------|---------------|
| Ingredient Name  | Basis of Strength | Strength      |
| PO VIDO NE-IO DINE (UNII: 85H0 HZU99 M) (IO DINE - UNII:9679 TC07X4) | IODINE            | 11 mg in 1 mL |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| NONOXYNOL-10 (UNII: K7O76887AP)                              |          |
| POTASSIUM IODIDE (UNII: 1C4QK22F9J)                          |          |
| WATER (UNII: 059QF0KO0R)                                     |          |
| ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)                    |          |
| GLYCERIN (UNII: PDC6 A3C0 OX)                                |          |
| HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16) |          |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)                          |          |

| Pac  | kaging          |   |                             |                    |
|------|-----------------|---|-----------------------------|--------------------|
| #    | Item Code       | Package Description                                   | <b>Marketing Start Date</b> | Marketing End Date |
| 1 NE | OC:59050-556-44 | 118 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 Moakang Medical Products Co. Ltd (421317073)

| Establishment                               |         |           |                        |  |
|---|---------|-----------|------------------------|--|
| Name  | Address | ID/FEI    | Business Operations    |  |
| Changzhou Moakang Medical Products Co., Ltd |         | 421317073 | manufacture(59050-556) |  |

Revised: 6/2020 Changzhou Moakang Medical Products Co. Ltd