# AMSURE THREE POVIDONE-IODINE SWABSTICKS- povidone-iodine swab Amsino International, Inc.

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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#### **Active Ingredient Section**

Active ingredient

Povidone Iodine USP, 10% W/V (equivalent to 1% tiratable iodine)

#### **Purpose Section**

Purpose Antiseptic

#### Stop Use Section

Stop use and ask a doctor if skin irritation, redness, swelling, or pain occurs.

#### **Warnings Section**

Warnings • Do not use if allergic to iodine • For external use only • Do not use in eyes • Avoid pooling beneath patient • In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

#### **Keep Out of Reach of Children Section**

Keep out of reach of children.

#### **Indications and Uses Section**

Uses antiseptic skin preparation

#### **Directions Section**

Directions apply locally as needed

#### **Inactive Ingredients Section**

Inactive ingredients Citric Acid, Glycerol, Nonoxynol-10, Sodium hydroxide, water

#### **Questions Section**

Questions? Call 1-800-632-6746

#### Other Information Section

Other information

For Hospital or Professional Use Only.

Store at room temperature: 15°C - 30°C

#### **Package Label**

#### AMSINO AMSure Three Povidone-Iodine Swabsticks NDC 67752-2003-3 REF PIS2003

Three 4-inch saturated swabsticks Sterile, unless opened or damaged DO NOT RE-USE LATEX-FREE

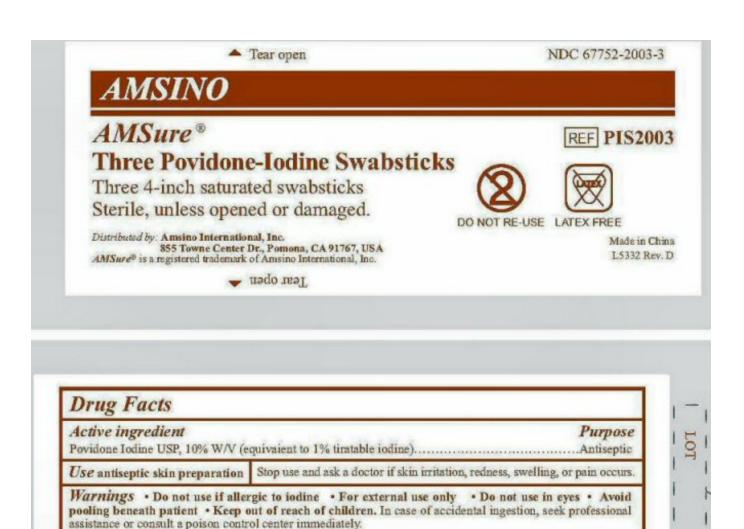
Distributed by: Amsion International, inc. 855 Towne Center Dr., Pomona, CA 91757, USA AMSure is a registered trademark of Amsino International, Inc. Made in China L5332 Rev. D

Tear open LOT EXP.

Directions apply locally as needed

For Hospital or Professional Use Only. Store at room temperature: 15°C 30°C

Other information



Inactive ingredients

Questions? Call 1-800-632-6746

hydroxide, water

Citric Acid, Glycerol, Nonoxynol-10, Sodium

#### AMSURE THREE POVIDONE-IODINE SWABSTICKS

povidone-iodine swab

Droduct	Information
FIVUUCL	IIIIVI IIIAUVII

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67752-2003

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

ı	Active ingredictionative without				
	Ingredient Name	Basis of Strength	Strength		
	Povidone-Iodine (UNII: 85H0 HZU99 M) (Povidone-Iodine - UNII:85H0 HZU99 M)	Po vido ne-Io dine	0.1 mg in 1 mL		

# Inactive Ingredients Ingredient Name Strength CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) GLYCERIN (UNII: PDC6A3C0OX) NONOXYNOL-10 (UNII: K7076887AP) SODIUM HYDROXIDE (UNII: 55X04QC32I) WATER (UNII: 059QF0K00R)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:67752-2003-3	6 mL in 1 POUCH		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333C	01/06/2012				

## Labeler - Amsino International, Inc. (825673239)

### **Registrant** - Amsino International, Inc. (825673239)

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