

**FOAM SAFE - povidone iodine liquid**  
**Gremed Manufacturing LLC**

*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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**DRUG FACTS**

**Active Ingredient                      Purposes**

Povidone Iodine 7.5% w/w ..... Antiseptic

**Uses**

Significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care.

**Warnings**

**For External Use Only**

**Stope use and ask doctor** if irritation or redness develops.

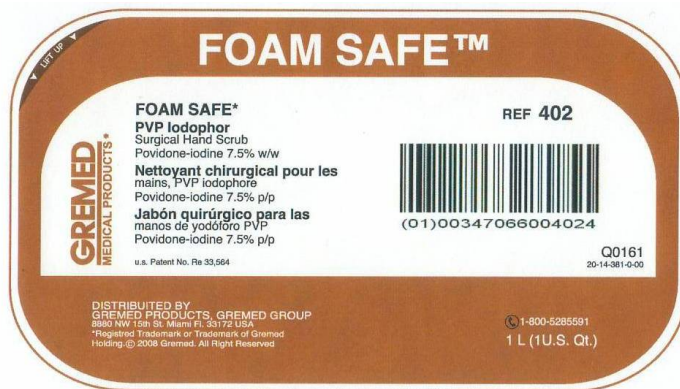
**Keep out of reach of children.**

**Directions**

Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Wet hands and forearms. Apply a palmful (5g) of foam to hands and forearms. Scrub thoroughly for 2 minutes with a sterile scrub brush, paying particular attention to the nails, cuticles and interdigital spaces. Rinse and repeat scrub.

**Inactive Ingredients**

Water, Lauramide DEA, Ammonium Lauryl Sulfate, PEG-7, Glyceryl Cocoate, Panthenol, Sodium Hydroxide, Potassium Iodate



Drug Facts	
<b>Active ingredient</b>	<b>Purposes</b>
Povidone iodine 7.5 % w/w	Antiseptic
<b>Uses</b> Significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care.	
<b>Warnings</b> For External Use Only	
<b>Stop use and ask a doctor</b> if irritation or redness develops.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a poison control center right away. Avoid contact with eyes; in case of contact, flush eyes with water.	
<b>Directions</b> Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Wet hands and forearms. Apply a palmful (5g) of foam to hands and forearms. Scrub thoroughly for 2 minutes with a sterile scrub brush, paying particular attention to the nails, cuticles, and interdigital spaces. Rinse and repeat scrub.	
<b>Inactive Ingredients</b> Water, Lauramide DEA, Ammonium Lauryl Sulfate, PEG-7 Glyceryl Cocoate, Panthenol, Sodium Hydroxide, Potassium Iodate	

*Ingrédients inactifs: voir ci-dessus  
Ingredientes inactivos: ver antes*

Au sujet des médicaments	
<b>Ingrédient actif:</b> Povidone Iodine 7.5% p/p	
<b>Usage:</b> Antiseptique	
<b>Utilisation:</b> Réduit considérablement le nombre de micro-organismes sur les mains et les avant-bras avant d'effectuer une chirurgie ou de traiter un patient.	
<b>Avertissement:</b> Pour usage externe seulement. Arrêter l'utilisation et consulter un médecin si une irritation ou une rougeur se produit. Ne pas laisser à la portée des enfants. Si une personne ingère ce produit, consulter un médecin ou communiquer immédiatement avec un centre antipoison. Éviter tout contact avec les yeux. En cas de contact, rincer les yeux à l'eau.	
<b>Instructions:</b> Nettoyer le dessous des ongles avec un bâtonnet pour les ongles. La partie blanche des ongles ne devrait pas dépasser un millimètre. Mouiller les mains et les avant-bras. Appliquer 5 g de savon sur les mains et les avant-bras. Frotter vigoureusement pendant 2 minutes avec une brosse à récurage stérile, en portant une attention particulière aux ongles, aux cuticules et à la peau entre les doigts. Rincer et répéter l'opération.	
<b>Información general</b> Ingredientes inactivos: Povidone Iodine 7.5% p/p Uso: Antiséptico Uso: Elimina considerablemente el número de microorganismos de las manos y antebrazos antes de cirugía o para la atención de pacientes. Advertencia: Para uso externo solamente. En caso de irritación o enrojecimiento, suspender el uso del producto y consultar a su médico. Conservar el producto fuera del alcance de los niños. Si un niño ingiere este producto, consultar a su médico o llamar al Centro de Control Tóxico. Evitar el contacto del producto con los ojos, en caso de contacto, enjuagarse con agua. Instrucciones: Limpiar las uñas con un palillo de madera. Las uñas deben estar cortadas a 1 milímetro de longitud. Mojar las manos y los antebrazos. Aplicarse 5 g de espuma en las manos y los antebrazos. Frotarse vigorosamente por 2 minutos con un cepillo quirúrgico estéril, sobre todo las uñas, la cutícula y los espacios interdigitales. Enjuagarse y repetir el procedimiento.	
<b>LOT</b> Use by Utiliser avant Úsese antes	<b>Q0161</b> 20-14-381-0-00

If swallowed, get medical help or contact a poison control center right away. Avoid contact with eyes; in case of contact, flush eyes with water.

FOAM SAFE			
povidone iodine liquid			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:470 66 -402
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0 HZU99 M) (POVIDONE-IODINE - UNII:85H0 HZU99 M)	POVIDONE-IODINE	7.5 mg in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0K00R)			
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)			
AMMONIUM LAURYL SULFATE (UNII: Q7A02R1M0B)			
POLYETHYLENE GLYCOL 350 (UNII: ZBR3T82M2V)			
GLYCERYL COCOATE (UNII: WVK1CT5994)			
PANTHENOL (UNII: WV9CM0O67Z)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
POTASSIUM IODATE (UNII: I139E44NHL)			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47066-402-01	59 mL in 1 BOTTLE		
2	NDC:47066-402-02	118 mL in 1 BOTTLE		
3	NDC:47066-402-03	473 mL in 1 BOTTLE		
4	NDC:47066-402-04	500 mL in 1 BOTTLE		
5	NDC:47066-402-05	1000 mL in 1 BOTTLE		
6	NDC:47066-402-06	3785 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/01/2012	

**Labeler** - Gremed Manufacturing LLC (832854041)

Revised: 4/2012

Gremed Manufacturing LLC