POVIDONE-IODINE- povidone-iodine solution Medline Industries, LP

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.

944 PVP Scrub Solution

Active Ingredient

Povidone-Iodine, 7.5% (equivalent to 0.75% available iodine)

Purpose

Antiseptic

Uses

- For preparation of the skin prior to surgery
- helps to reduce bacteria that potentially can cause skin infection
- significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care

Warnings

For external use only.

Do not use

- in the eyes
- if you are allergic to iodine or any of the other ingredients in the product.

When using this product

- prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions
- in pre-operative prepping, avoid "pooling" beneath the patient.

Stop use and ask a doctor

- if irritation and redness develop
- if condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Surgical Hand Scrub:

- Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge.
- Wet hands and forearms
- Apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- Scrub thoroughly for about 5 minutes paying particular attention to the nails, cuticles, and interdigital spaces
- Use a sterile scrub brush, if desired
- Rinse and repeat scrub

Patient Pre-operative Skin Preparation:

- Prior to surgery, wet skin with water
- Apply scrub to the operative site
- scrub thoroughly for about 5 minutes
- Rinse using sterile gauze or towel, or remove with 70 percent alcohol
- follow with application of Medline Prep Solution and allow to dry

Other Information

Store at Room Temperature. Protect from freezing. Avoid excessive heat.

Inactive Ingredients

Disodium Phosphate, Glycerin, Hydroxy Ethyl Cellulose, Monoethanolamine, Water

Manufacturing Information

Manufactured for: Medline Industries, LP Three Lakes Drive, Northfield, IL 60093 USA Made in Mexico www.medline.com 1-800-MEDLINE (633-5463) REF: 500762 V1 RK22DEG

Package Label

MEDLINE	Drug Facts
NDC 53329-944-04	Active Ingredient Purpose Povidone-Iodine, 7.5% (equivalent to 0.75% available iodine)Antiseptic
	Uses ■ For preparation of the skin prior to surgery ■ helps to reduce bacteria that potentially can cause skin infection ■ significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
PVP SCRUB SOLUTION	Warnings For external use only. Do not use ■ in the eyes ■ if you are allergic to iodine or
ANTISEPTIC SKIN CLEANSER 7.5% POVIDONE-IODINE	any of the other ingredients in the product. When using this product = prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions = in pre-operative prepping, avoid "pooling" beneath the patient. Stop use and ask a doctor = if irritation and redness develop = if condition persists for more than 72 hours Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.
Single use only. Not made with natural rubber latex. 4 fl. oz. (118 ml)	Directions Surgical Hand Scrub: Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Wet hands and forearms Apply 5 milliliters (teaspoonful) or palmful to hands and forearms Scrub thoroughly for about 5 minutes paying particular attention to the nails, cuticles, and interdigital spaces Use a sterile scrub brush, if desired Rinse and repeat scrub Patient Pre-operative Skin Preparation:
Exp: REF 500762	Prior to surgery, wet skin with water Apply scrub to the operative site scrub thoroughly for about 5 minutes Rinse using sterile gauze or towel, or remove with 70 percent alcohol follow with application of Medline Prep Solution and allow to dry
	Other Information Store at Room Temperature. Protect from freezing. Avoid excessive heat. Inactive Ingredients Disodium Phosphate, Glycerin, Hydroxy Ethyl Cellulose,
(01)10080196995448	Monoethanolamine, Water www.medline.com Manufactured for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA Made in Mexico To Order Call: 1-800-MEDLINE V1 RK22DEG
POVIDONE-IODINE	
ovidone-iodine solution	
Product Information	

Prod	uct	Туре	

Item Code (Source)

Route of Administration TOPICAL

NDC:53329-944

HUMAN OTC DRUG

Active Ingredient/Active Moiety Ingredient Name Basis of Strength

Strength **POVIDONE-IODINE** (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) IODINE 7.5 mg in 1 mL

Inactive Ingredients

Ingredient Name		Strength
WATER (UNII: 059QF0KO0R)		
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)		
GLYCERIN (UNII: PDC6A3C0OX)		
MONOETHANOLAMINE (UNII: 5KV86114PT)		
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP))	
Packaging		

Marketing Start Marketing End Item Code **Package Description** # Date Date NDC:53329-944- 118 mL in 1 BOTTLE; Type 0: Not a Combination

• 04	Product	11/04/2010			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	11/04/2016			

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 12/2022

Medline Industries, LP