

PROVODINE- providone iodine emulsion
Microdermis Corporation

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.

Provodine

Active ingredient

Povidone-iodine 7.5%

Purpose

Antiseptic

Uses

- **Patient Preoperative Skin Preparation:** for preparation of the skin prior to a procedure. Helps reduce bacteria that potentially can cause skin infection.
- **Surgical Hand Scrub:** significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care.
- **Healthcare Personnel Handwash:** for handwashing to decrease bacteria on the skin after assisting ill persons.

Warnings

For external use only

Do not use in the eyes

Stop use and ask a doctor if

irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center 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 60 seconds, paying particular attention to the nails, cuticles, and interdigital spaces.
- Rinse and repeat scrub. ■ Dry with a clean towel.

Patient Preoperative Skin Preparation:

- Clean the area.

- Apply product to the operative site prior to surgery.
- 1 mL (dime size) covers an estimated 5”x5” area.
- Let dry 1-2 minutes.

Healthcare Personnel Handwash Without Water:

- Place a smaller amount (3 mLs) of product in one hand.
- Spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds).

Healthcare Personnel Handwash With Water:

- Wet clean hands and wrists.
- Apply 3 milliliters into one hand and spread over both hands to wrist.
- Rub thoroughly for 30 seconds.
- Let dry for 30 seconds.
- Rinse for 30 seconds.
- Dry with a clean towel.

Other Information

Store in a cool dry place, between 20°-25° C (66°-77° F)

Avoid freezing and excessive heat above 40° C (104° F)

Inactive Ingredients

Allantoin, Beeswax, Benzalkonium Chloride, Butylene, Glycol, C13-14 Isoparaffin, Caprylic/Capric, Triglyceride, Cetyl Alcohol, Disodium EDTA, Distearyl, Dimonium Chloride, Emulsifying Wax, NF, Glyceryl, Laurate, Glyceryl Stearate, Hydrogenated Jojoba Esters, Laureth-7, Nonoxynol-9, Octoxynol-9, PCA, PEG-100 Stearate, Polyacrylamide, Polyglyceryl-3 Diisostearate, Polyquaternium-7, Purified Water, Sclerotium Gum, Stearic Acid, Triethanolamine.

Questions?

Call (877) 710-6958 www.microdermis.com

Package/Label Principal Display Panel

NDC 59426-001-16
For Professional Use Only

[®]
Providence

- Surgical Hand Scrub
- Patient Preoperative Skin Preparation

- Healthcare Personnel Handwash

Povidone Iodine 7.5%

Exceedingly *Effective*

Remarkably *Persistent*

Surprisingly *Gentle on the Skin*

- Non-irritating
- Clinically-proven hydration
- Active for up to 6 hours
- Leaves skin soft and clean

 **microdermis**

Microdermis Corporation
103 Carnegie Center, Suite 300
Princeton, NJ 08540 Made in USA

16 fl oz (473 mL)

Drug Facts

Active Ingredient	Purpose
Povidone-iodine 7.5%	Antiseptic

Uses

- **Patient Preoperative Skin Preparation:** for preparation of the skin prior to a procedure. Helps reduce bacteria that potentially can cause skin infection.
- **Surgical Hand Scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care.
- **Healthcare Personnel Handwash:** for handwashing to decrease bacteria on the skin after assisting ill persons.

Warnings

- For external use only.
- Do not use in the eyes.
- Stop use and ask a doctor if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center 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 60 seconds, paying particular attention to the nails, cuticles, and interdigital spaces. ■ Rinse and repeat scrub. ■ Dry with a clean towel.

Patient Preoperative Skin Preparation: ■ Clean the area. ■ Apply product to the operative site prior to surgery. ■ 1 mL (dime size) covers an estimated 5"x5" area. ■ Let dry 1-2 minutes.

Healthcare Personnel Handwash Without Water: ■ Place a smaller amount (3 mLs) of product in one hand. ■ Spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds).

Healthcare Personnel Handwash With Water: ■ Wet clean hands and wrists. ■ Apply 3 milliliters into one hand and spread over both hands to wrist. ■ Rub thoroughly for 30 seconds. ■ Let dry for 30 seconds. ■ Rinse for 30 seconds. ■ Dry with a clean towel.

Other Information

Store in a cool dry place, between 20°-25° C (66°-77° F) Avoid freezing and excessive heat above 40° C (104° F)

Inactive Ingredients

Allantoin, Beeswax, Benzalkonium Chloride, Butylene Glycol, C13-14 Isoparaffin, Caprylic/Capric Triglyceride, Cetyl Alcohol, Disodium EDTA, Distearyl Dimonium Chloride, Emulsifying Wax, NF, Glyceryl Laurate, Glyceryl Stearate, Hydrogenated Jojoba Esters, Laureth-7, Nonoxonyl-9, Octoxynol-9, PCA, PEG-100 Stearate, Polyacrylamide, Polyglyceryl-3 Distostearate, Polyquaternium-7, Purified Water, Sclerotium Gum, Stearic Acid, Triethanolamine

Questions?

Call (877) 710-8958 www.microdermis.com



 **microdermis**

Microdermis Corporation
103 Carnegie Center, Suite 300
Princeton, NJ 08540
877.710.6958
www.microdermis.com

For professional use only

NDC 59426-001-03
Not For Resale



Providence

Povidone Iodine 7.5%

- Surgical Hand Scrub • Healthcare Personnel Handwash
- Patient Preoperative Skin Preparation

0.10 fl oz (3.0 mL)

- Surgical Hand Scrub • Healthcare Personnel Handwash
 - Patient Preoperative Skin Preparation
- 100 Packettes - 0.10 fl oz (3.0 mL) Each
Net Contents 10 fl oz (300 mL)

Provodine®

Povidone Iodine 7.5%



Microdermis Corporation
103 Carnegie Center, Suite 300
Princeton, NJ 08540
877.710.6958
www.microdermis.com
Made in USA

Drug Facts	Purpose
Active Ingredient Povidone-iodine 7.5%	Antiseptic
Uses	<ul style="list-style-type: none"> ■ Patient Preoperative Skin Preparation: for preparation of the skin prior to a procedure, helps reduce bacteria that can enter the body during surgery. ■ Surgical Hand Scrub: helps reduce the number of micro-organisms on the hands and forearms prior to surgery or patient care. ■ Healthcare Personnel Handwash: for handwashing to decrease bacteria on the skin after assisting ill persons.
Warnings	<ul style="list-style-type: none"> ■ Do not use in the eyes. ■ For external use only. ■ Stop use and ask a doctor if irritation and redness develop. If condition persists for more than 72 hours consult a doctor. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions	<p>Surgical Hand Scrub: Clean under nails with a nail pick. Nails should be scrubbed with a 1 millimeter free edge. Wet hands and forearms. Apply 5 milliliters (half packet) of product to hands and forearms. Scrub thoroughly for 60 seconds, paying particular attention to the nails, cuticles, and interdigital spaces. Rinse and repeat scrub. Dry with a clean towel.</p> <p>Patient Preoperative Skin Preparation: Clean the area. Apply product to the operative site prior to surgery.</p>

Drug Facts (cont.)	Other Information
<ul style="list-style-type: none"> ■ 1 mL (dime size) covers an estimated 5"x5" area. ■ Let dry 1-2 minutes. ■ Healthcare Personnel Handwash Without Water: Place a smaller amount (3 mL) of product in one hand. Spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds). ■ Spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds). <p>Healthcare Personnel Handwash With Water: Wet clean hands and wrists. Apply 3 milliliters into one hand and spread over both hands to wrist. Rub thoroughly for 30 seconds. Let dry for 30 seconds. Rinse for 30 seconds. Dry with a clean towel.</p>	<p>Store in a cool dry place between 20°-28° C (68°-77° F). Avoid freezing and excessive heat above 40° C (104° F).</p> <p>Inactive Ingredients Aluminum, Benzene, Benzalkonium Chloride, Butylene Glycol, C13-14 Isoparaffin, Capryl/Capric Triglyceride, Cetyl Alcohol, Chondrus EDTA, Disodium Dimethyl Chloride, Emulsifying Wax, NF, Glyceryl Laurate, Glyceryl Stearate, Hydrogenated Jojoba Esters, Laurate-7, Nonoxonyl-8, Octylenol-8, PCA, PEG-100 Stearate, Polyquaternium-7, Purified Water, Scedonium Gum, Stearic Acid, Triethanolamine</p>
Questions?	
Call (877) 710-6958 www.microdermis.com	

Provodine®
Povidone Iodine 7.5%

- Surgical Hand Scrub • Healthcare Personnel Handwash
- Patient Preoperative Skin Preparation

Exceedingly Effective Remarkably Persistent Surprisingly Gentle on the Skin

• Non-irritating • Active for up to 6 hours • Clinically-proven hydration • Leaves skin soft and clean

100 Packettes - 0.10 fl oz (3.0 mL) Each
Net Contents 10 fl oz (300 mL)

NDC 59426-001-03

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- Surgical Hand Scrub • Healthcare Personnel Handwash
- Patient Preoperative Skin Preparation

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Net Contents 10 fl oz (300 mL)

PROVODINE			
povidone iodine emulsion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59426-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0 HZU99M) (IODINE - UNII:9679 TC07X4)	IODINE	7.5 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ALLANTOIN (UNII: 344S277G0Z)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CETYL ALCOHOL (UNII: 936JST6JCN)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
GLYCERYL LAURATE (UNII: Y98611C087)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
LAURETH-7 (UNII: Z95S6G8201)
NONOXYNOL-9 (UNII: 48Q180SH9T)
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)
PIDOLIC ACID (UNII: SZB83O1W42)
PEG-100 STEARATE (UNII: YD01N1999R)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)
WATER (UNII: 059QF0KO0R)
BETASIZOFIRAN (UNII: 2X51AD1X3T)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59426-001-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59426-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59426-001-03	100 in 1 BOX		
3		3 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/15/2014	

Labeler - Microdermis Corporation (969967988)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, Inc		061595175	MANUFACTURE(59426-001)

Establishment

Name	Address	ID/FEI	Business Operations
ACUPAC PACKAGING INC		037138013	manufacture(59426-001)