

APOCREME- povidone 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.

Apocreme

Drug Facts

Active ingredient

Povidone Iodine 7.5%

Purpose

First Aid Antiseptic

Uses

First aid to help reduce bacterial contamination in minor cuts, scrapes, and burns

Warnings

For external use only.

Do not use

- In the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor
- Longer than 1 week unless directed by a doctor

Stop use and ask a doctor

If the condition persists or gets worse.

Keep out of reach of children.

In case of accidental overdose, contact a medical professional or a Poison Control Center immediately.

Directions

- Clean the affected area.
- Apply a small amount of this product on the area 1 to 3 times daily.
- May be covered with a sterile bandage.
- If bandaged, let dry first.

Other information

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

Avoid freezing and excessive heat above 40^o C (104^o 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 (855) 848-5599 www.apocrema.com

Product Label

Apocrème™

NDC 59426-002-04


**First Aid Antiseptic
Povidone Iodine 7.5%**

- Reduce Bacterial Contamination
- Help to Prevent The Risk of Skin Infection in Minor Cuts, Scrapes, and Burns
- Hypo-allergenic
- Non Irritating
- Antiseptic Effect Lasts For Hours

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Drug Facts (continued)	
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4 fl oz (118 mL)



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MC012-01

Apocrème™

First Aid Antiseptic
Povidone Iodine 7.5%



Apocrème™ proudly features Microdermis' Amidermal® Platform, an innovative technology based on more than a decade of research and development to enable precise targeted delivery of medicine to the skin.

Amidermal significantly enhances performance and improves safety, resulting in better products and, ultimately, better healthcare.

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

MC013-01



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APOCREME

povidone iodine emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59426-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	75 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: SZB8301W42)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
WATER (UNII: 059QF0K00R)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59426-002-04	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/21/2015	

Labeler - Microdermis Corporation (969967988)

Revised: 6/2015

Microdermis Corporation