HYPOCYN- dressing, wound, drug Summers Laboratories, Inc.

HypoCyn™ Antimicrobial Dermal Spray Solution

INDICATIONS FOR USE:

HypoCyn[™] Antimicrobial Dermal Spray Solution is intended to be used under the supervison of a health care professional for cleaning and removal of microorganisms, debris, and foreign material affecting various dermatologic skin conditions. Apply HypoCyn[™] Antimicrobial Dermal Spray Solution liberally on site to clean. Do not remove or wipe off. If use of dressing is required, apply liberally to dressing. No rinsing is required.

DIRECTIONS FOR USE:

Spray HypoCyn[™] Antimicrobial Dermal Spray Solution to the affected area 2 times daily, or as directed by a healthcare professional.

DESCRIPTION:

HypoCyn[™] Antimicrobial Dermal Spray Solution is a proprietary skin solution containing balanced analytic hypochlorous acid as a preservitive, which is know to be safe and fast acting in the removal of microorganisms of the skin.

CONTRAINDICATIONS:

Check for known hypersensitivity to any of the HypoCyn[™] Antimicrobial Dermal Spray Solution ingredients.

STORAGE:

Keep away from direct sunlight and heat sources. Do Not Freeze.

HANDLING AND DISPOSAL:

HypoCyn[™] Antimicrobial Dermal Spray Solution is non-irritating, non-cytotoxic and non-sensitizing to skin. Special handling or disposal precautions are not required.

SAFETY:

HypoCyn[™] Antimicrobial Dermal Spray Solution is non-irritating and non-sensitizing, having passed bio-compatibility studies including ISO ocular irritation and ISO Maximum Sensitivity test.

WARNINGS AND PRECAUTIONS:

For external use only. Do not use for infusion or injection. Do not swallow. If you experience redness, swelling, irritation or pain, discontinue use and contact your doctor. In case of sensitivities to chlorine, please exercise caution and consult with your doctor prior to use. Do not use expired product.

HOW SUPPLIED:

HypoCyn[™] Antimicrobial Dermal Spray Solution is supplied in an 8 fl. oz. (237ml) bottle.

KEEP OUT OF THE REACH OF CHILDREN.

DOES NOT CONTAIN ANTIBIOTICS, STEROIDS, PEROXIDE OR ALCOHOL

CONTRAINDICATIONS: CHECK FOR KNOWN HYPERSENSITIVITY TO ANY OF THE HYPOCYN™ ANTIMICROBIAL DERMAL SPRAY SOLUTION INGREDIENTS.

STORAGE: KEEP AWAY FROM DIRECT SUNLIGHT AND HEAT SOURCES. DO NOT FREEZE.

HANDLING AND DISPOSAL: HYPOCYN™ ANTIMICROBIAL DERMAL SPRAY SOLUTION IS NON-IRRITATING, NON-CYTOTOXIC AND NON-SENSITIZING TO SKIN. SPECIAL HANDLING OR DISPOSAL PRECAUTIONS ARE NOT REQUIRED.

HOW SUPPLIED: HYPOCYN™ ANTIMICROBIAL DERMAL SPRAY IS AVAILABLE IN AN 8 0Z SPRAY SOLUTION. SAFETY: HYPOCYN™ ANTIMICROBIAL DERMAL SPRAY SOLUTION IS NON-IRRITATING AND NON-SENSITIZING, HAVING PASSED BIO-COMPATIBILITY STUDIES INCLUDING ISO OCULAR IRRITATION AND ISO MAXIMUM SENSITIVITY TEST.

WARNINGS AND PRECAUTIONS: FOR EXTERNAL USE ONLY. DO NOT USE FOR INFUSION OR INJECTION. DO NOT SWALLOW. IF YOU EXPERIENCE REDNESS, SWELLING, IRRITATION OR PAIN, DISCONTINUE USE AND CONTACT YOUR DOCTOR. IN CASE OF SENSITIVITIES TO CHLORINE, PLEASE EXERCISE CAUTION AND CONSULT WITH YOUR HEALTHCARE PROFESSIONAL PRIOR TO USE. DO NOT USE EXPIRED PRODUCT.

KEEP OUT OF THE REACH OF CHILDREN.



HYPOCYN

dressing, wound, drug

Product Information								
Pr	oduct Type	PRESCRIPTION MEDICAL DEVICE	ltem Co	de (Source)	NHRIC:11086-058			
Packaging								
#	ltem Code	Package Description		Marketing Start Date	Marketing End Date			
	NHRIC:11086- 058-01	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	I					

Marketing In	larketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
premarket notification	K113693	03/14/2022					

Labeler - Summers Laboratories, Inc. (232386772)

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Summers Laboratories, Inc.