HYCLODEX- dressing, wound, drug Marnel Pharmaceuticals, Inc.

Hyclodex

INDICATIONS FOR USE:

 $Hyclodex^{TM}\,Rx\ is\ intented\ to\ be\ used\ under\ the\ supervison\ of\ a\ health\ care\ professional\ for\ cleaning\ and\ removal\ of\ microorganisms,\ debris,\ and\ foreign\ material\ affecting\ various\ dermatologic\ skin\ conditions.\ Apply\ Hyclodex^{TM}\ solution\ liberally\ on\ site\ to\ clean.\ Do\ not\ remove\ or\ wipe\ off.\ If\ use\ of\ dressing\ is\ required,\ apply\ liberally\ to\ dressing.\ No\ rinsing\ is\ required.$

DOES NOT CONTAIN ANTIBIOTICS, STEROIDS, PEROXIDE OR ALCOHOL.

For Topical Use Only - Rx Only

PRODUCT SUMMARY: Hyclodex^{©TM} is a proprietary skin solution containing balanced analytic hypochlorious acid as a preservative, which is known to be safe and fast acting in the removal of microorganisms of the skin.

CONTRAINDICATIONS: Check for known hypersensitivity to any of the Hyclodex^{IITM} solution ingredients.

DIRECTIONS OF USE: Spray Hyclodex^{ITM} on a clean gauze pad. Thoroughly apply to affected areas and allow product to fully dry on skin. Apply product 2 times per day or as directed.

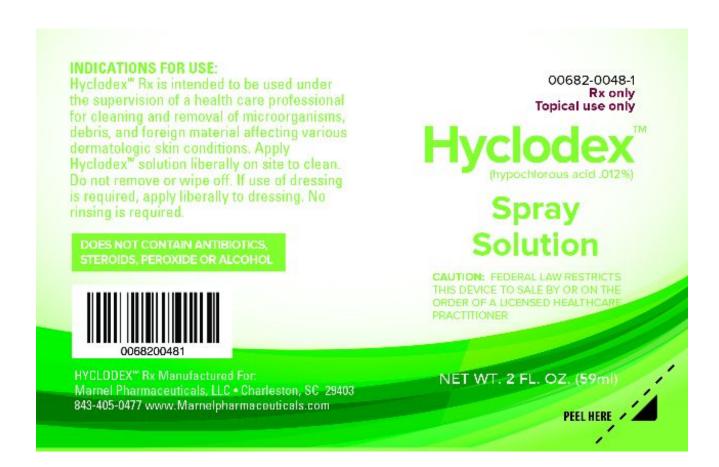
STORAGE: Store at a controlled room temperature of 65⁰ to 75⁰ F. Keep away from direct sunlight and heat sources. Do Not Freeze.

Handling and Disposal: $Hyclodex^{\parallel TM}$ is non-irritating, non-cytoxic and nonsensitizing to skin and eyes. Special handling or disposal precautions are not required.

SAFETY: Hyclodex^{||}TM is non-irritating and nonsensitizing 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. Keep out of reach of children.

HOW SUPPLIED: Hyclodex^{ITM} is available in 59 ml spray solution.



HYCLODEX

dressing, wound, drug

Product Information

Product Type PRESCRIPTION MEDICAL DEVICE Item Code (Source) NHRIC:00682-0048

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NHRIC:00682- 0048-1	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
premarket notification	K113693	02/26/2018			

Labeler - Marnel Pharmaceuticals, Inc. (080161449)

Revised: 3/2018 Marnel Pharmaceuticals, Inc.