

VASCUDERM HYDROGEL WOUND DRESSING- dressing,wound,hydrogel w/out drug and/or biologic
Primus Pharmaceuticals, Inc

Home Use Medical Device

Description

VASCUDERM Hydrogelgel Wound Dressing is a non-oily hydrogel intended for the management of wounds.

Ingredients

Aloe acetylated mannan polysaccharide, Aloe acetylated mannan polysaccharide high molecular weight, Carbomer 940, Citric acid, Disodium EDTA, DL-Panthenol, Imidazolidinyl urea, L-glutamic acid, Methylparaben, Potassium sorbate, Purified water, PVP, Sodium benzoate, Sodium chloride, Sodium metabisulfite, Triethanolamine.

Summary of Safety and Effectiveness

The product is for topical use. The safety of the gel was established through standard biocompatibility tests. These biocompatibility tests were conducted in standard animal models with preparation of the VASCUDERM Hydrogel Wound Dressing. These tests included Primary Dermal Irritation testing and Primary Eye Irritation testing. These studies demonstrated that Vascuderm hydrogel are not primary dermal irritants or primary eye irritants. These studies were conducted in conformance with Good Laboratory Practices (GLP) regulations of the United States Food and Drug Administration (21 CFR, Part 58).

Clinical experience to date has been gained during the course of two studies that involved four patients with radiation dermatitis and 30 with diabetic ulcers. Grades III or IV diabetic ulcers of the foot were treated with VASCUDERM Hydrogel Wound Dressing for 10 weeks. Acute and subacute radiation dermatitis was treated for various times with VASCUDERM Hydrogel Wound Dressing. These studies evaluated the acceptability of VASCUDERM Hydrogel Wound Dressing to both patients and clinicians, to wound and skin appearance, and to the wound healing environment. These studies concluded that VASCUDERM Hydrogel Wound Dressing is safe and effective for its intended use.

Indications

VASCUDERM Hydrogel Wound Dressing is indicated for use in the management of: Stasis Ulcers, Foot Ulcers, Diabetic Ulcers, Pressure Ulcers, Surgical Incisions, Skin Conditions associated with Peristomal Care, Cuts and Abrasions, First and Second Degree Burns, Radiation Dermatitis, and Sunburn.

Directions for Use

Flush wound with a suitable wound cleanser. Pat wound dry before applying VASCUDERM Hydrogel Wound Dressing. Apply sufficient amount of VASCUDERM Hydrogel Wound Dressing to cover area, including wound margins. Apply as often as needed. If gauze is used as a wound covering, it should be moistened with a suitable wound cleanser as recommended by a physician.

This product may turn amber in color, a natural phenomenon having no impact on efficacy. Intended for single patient use only.

PRECAUTION: Reduce the possibility of contamination by restricting use of each individual tube of VASCUDERM Hydrogel Wound Dressing to only one patient.

Warnings

If condition worsens or does not improve within 10-14 days, consult a physician. Keep this and all similar products out of the reach of children. Discontinue use if sensitivity occurs.

Adverse Reactions

Sensitivity to VASCUDERM Hydrogel Wound Dressing is infrequent. If a reaction is observed, discontinue use and consult a physician. Consult a physician for assistance with wounds that do not heal normally.

How Supplied

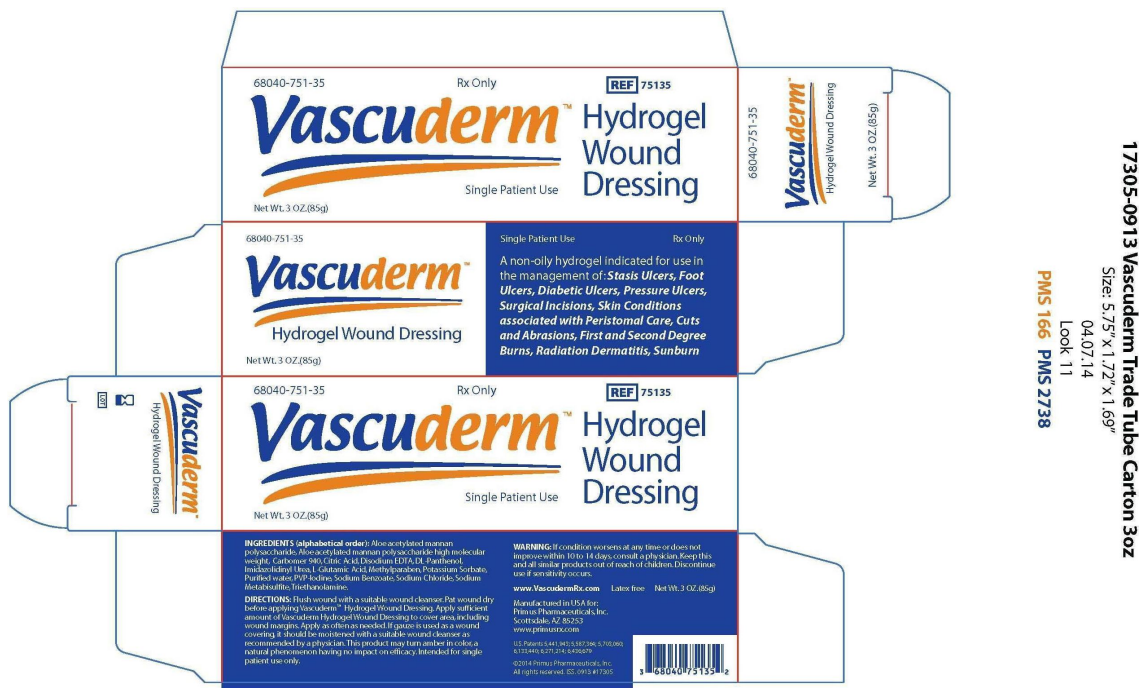
Package #	Description
68040-751-35	85 gram tube
68040-751-04	5 gram pouch sample - <i>not for resale</i>

Each 5 gram sample pouch contains multiple doses depending on the surface area treated.

Storage

Store in a dry place and at room temperature.

Principal Display Panel



VASCUDERM HYDROGEL WOUND DRESSING

dressing, wound, hydrogel w/out drug and/or biologic

Product Information			
Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:68 040-751
Other Ingredients			
Ingredient Kind	Ingredient Name	Quantity	
INGR	ACEMANNAN (UNII: UZ29E6L2X8)		
INGR	ACEMANNAN (80000 MW) (UNII: N2CFZ4168Y)		
INGR	CARBOMER 940 (UNII: 4Q93RCW27E)		
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)		
INGR	PANTHENOL (UNII: WV9CM067Z)		
INGR	IMIDUREA (UNII: M629807ATL)		
INGR	GLUTAMIC ACID (UNII: 3KX376GY7L)		
INGR	METHYL PARABEN (UNII: A2I8C7HI9T)		
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
INGR	WATER (UNII: 059QF0K00R)		
INGR	POVIDONE (UNII: FZ989GH94E)		

INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:68040-751-35	85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K960428	09/01/2014	

Labeler - Primus Pharmaceuticals, Inc (130834745)

Establishment

Name	Address	ID/FEI	Business Operations
Medline Industries, Inc		025460908	manufacture

Revised: 11/2014

Primus Pharmaceuticals, Inc