

ZENPHOR WOUND PAD- elastomer, silicone, for scar management patch
Beijing HKKY Medical Tech. Co., Ltd.

71073_212_Zenphor Wound Pad

Description

ZENPHOR WOUND PAD is a non-sterile nonresorbable occlusive wound dressing intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material with an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

Each **ZENPHOR WOUND PAD** contains: Urea, Phenyl Trimethicone, Aloe Vera Gel, Glycerol, Sodium Polyacrylate, Tartaric Acid, EDTA Disodium Salt, Polyacrylic Acid, Hyaluronic Acid, Hydrocotyle Asiatica Extract, and Water.

INDICATIONS AND USES

It is intended to provide a moist wound healing environment to facilitate the normal wound healing process.

Contraindications

ZENPHOR WOUND PAD is contraindicated in patients with known hypersensitivity to any of the listed ingredients.

Warnings

For external use only. If irritation occurs, discontinue use and consult your physician. Do not use in patients with known hypersensitivity to any of the listed ingredients. Store at 20°-25°C (68° to 77°F); Keep away from heat and protect from freezing. [See USP Controlled Room Temperature.]

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN

Precautions

Stop use and ask a doctor if irritation develops. In rare instances, silicone sheets may cause a rash on the skin. If ingested, get medical help or contact Poison Control Center right away.

This medication should be used as directed by your physician during pregnancy or while breastfeeding. Consult your doctor about the risks and benefits.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Adverse Reactions

On rare occasions, the pads may cause temporary redness, stinging, burning or irritation and normally disappear when the medication is discontinued.

Dosage and Administration

Wash hands before use and ensure that the wound area is clean. Peel off the backing of the pad and place the sticky side down on the affected area once daily. If needed, cut the pad to size making sure to leave at least 1/4" beyond the affected area. Change the hydrogel pad once a day until no longer needed.

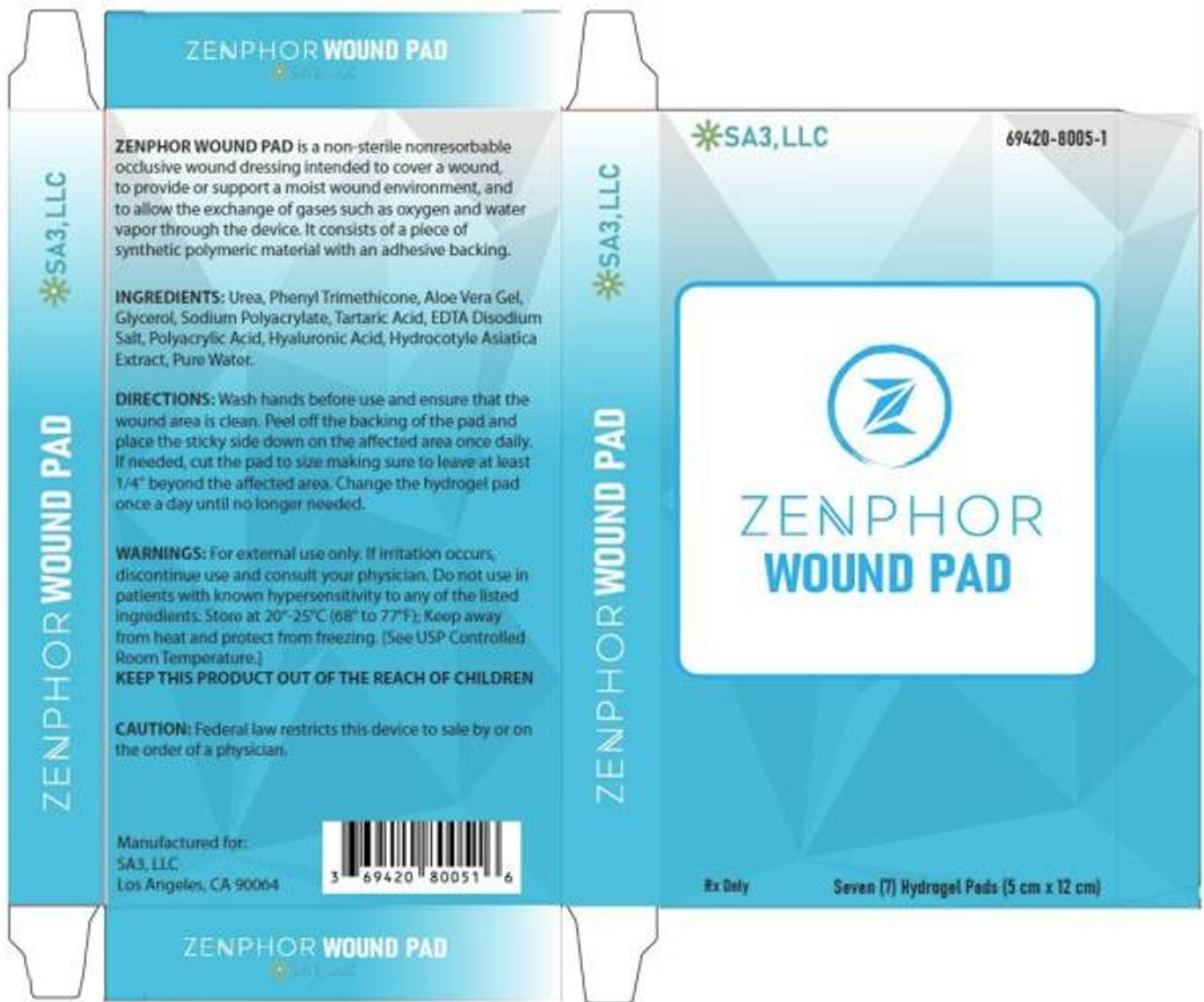
How is ZENPHOR WOUND PAD Supplied

ZENPHOR WOUND PAD is supplied in:
Seven (7) Non-Sterile Hydrogel Pads - in 1 Carton
69420-8005-1

Store at 20°-25°C (68° to 77°F); Keep away from heat and protect from freezing. [See USP Controlled Room Temperature.]

Manufactured for:

SA3, LLC
Los Angeles, CA 90064



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Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:71073-212
Route of Administration	TOPICAL		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71073-212-01	7 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
Exempt device	NAD	10/14/2021	

Labeler - Beijing HKKY Medical Tech. Co., Ltd. (544434817)

Establishment

Name	Address	ID/FEI	Business Operations
Beijing HKKY Medical Tech. Co., Ltd.		544434817	manufacture

Revised: 10/2021

Beijing HKKY Medical Tech. Co., Ltd.