

ZENPHOR WOUND- oral wound dressing
Beijing HKKY Medical Tech. Co., Ltd.

71073-211, Zenphor Wound Gel

Description

ZENPHOR WOUNDGEL 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.

ZENPHOR WOUNDGEL is a self-drying, flexible, gas permeable, gel that is colorless and odorless. It is intended to provide a moist wound healing environment to facilitate the normal wound healing process.

INGREDIENTS

ZENPHOR WOUNDGEL contains: Allantoin, Sulfadiazine, Aloe Vera Gel, Glycerol, Sodium Polyacrylate, Tartaric Acid, EDTA Disodium Salt, Hydroxyethyl Cellulose, Hyaluronic Acid, Hydrocotyle Asiatica Extract, and Pure Water.

INDICATIONS AND USES

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

Contraindications

ZENPHOR WOUNDGEL 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 gel may cause temporary redness, stinging, burning or irritation and normally disappear when the medication is discontinued.

Dosage and Administration

Ensure that the wound area is clean. Apply the gel to the affected area as a very thin coat and allow it to dry. Apply once daily.

How is ZENPHOR WOUNDGEL Supplied

ZENPHOR WOUNDGEL is supplied in:

30 gram bottle

69420-8004-1

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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Rx Only 30 gram

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ZENPHOR WOUND

oral wound dressing

Product Information

Product Type

MEDICAL DEVICE

Item Code (Source)

NHRC:71073-211

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71073-211-01	30 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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: 9/2021

Beijing HKKY Medical Tech. Co., Ltd.