

**ZENPHOR WOUND- oral wound dressing gel
SA3, LLC**

Zenphor Wound Gel

**ZENPHOR WOUND GEL
SA3, LLC**

**ZENPHOR WOUND GEL
Rx only
For external use only
Not for ophthalmic use**

Description

ZENPHOR WOUND GEL 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 WOUND GEL 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 WOUND GEL 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 WOUND GEL 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 WOUND GEL Supplied

ZENPHOR WOUND GEL 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

PRINCIPAL DISPLAY PANEL

ZENPHOR WOUND GEL

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Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:69420-8004
Route of Administration	TOPICAL		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69420-8004-1	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	08/23/2021	

Labeler - SA3, LLC (079627454)