

**POLYTOZA- elastomer, silicone, for scar management**  
**Sterling-Knight Pharmaceuticals, LLC**

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**Polytoza**  
**Silicone Gel Patch 100%**

**Rx Only (Prescription Only)**

Polytoza is colorless and odorless, flexible and waterproof external patch comprised of 100% Silicone in a gel base. Polytoza is intended for non-invasive management of old and new hypertrophic or keloid scars resulting from burns, surgical procedures or trauma wounds.

**Clinical Pharmacology**

The exact mechanism of silicone gel patches in improving the appearance of scar tissue remains unknown. However, numerous mechanisms have been suggested to explain the efficacy of silicone gel patch, including hydration, pressure, temperature, oxygen transmission and silicone absorption. There is some evidence that the treatment affects the stratum corneum and, by reducing evaporation, restores better homeostasis in the tissue. In keloid and hypertrophic scarring, the stratum corneum allows more evaporation of water from the underlying tissue than occurs in normal skin. Silicone patches may prevent this, keeping the stratum corneum in optimal hydration and protecting the skin from environmental hazards, both of which can reduce abnormal scarring. The silicone gel patch may also affect the stratum corneum by inhibiting mast cell activity, diminishing edema, vasodilatation and excessive extracellular matrix formation but the simple changes in temperature, pressure, oxygen tension and hydration produced by wound coverage probably constitute the main mechanism of action. Another hypothesis is that the effect of static electricity on silicone may influence the alignment of collagen deposition.

**Indication and Uses**

For external use only. Polytoza is intended for non-invasive management of old and new hypertrophic or keloid scars resulting from burns, surgical procedures or trauma wounds. It is effective for the management of both existing and new hypertrophic or keloid scars and as a prophylactic treatment on closed wounds.

**Contraindications**

Polytoza is contraindicated in patients with known hypersensitivity to silicone or any of the listed ingredients.

**Warnings**

For external use. Do not apply to an open wound or third degree burn. Never use on a sutured wound until sutures have been removed. In rare instances, silicone patch may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the silicone patch has been applied. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician.

**Ingredients**

Each Polytoza patch contains: 100% Silicone as Polysiloxane (5.2 grams of Silicone) in a gel base.

## **Precautions**

Stop use and ask a doctor if irritation develops. In rare instances, silicone sheets may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the silicone patch has been applied. If this product is applied properly and skin irritation still occurs, discontinue use and consult your physician. If ingested, get medical help or contact Poison Control Center right away. **KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

## **Caution:**

Federal law restricts this device to sale by or on the order by a licensed healthcare practitioner.

## **Adverse Reactions**

Polytoza may cause transient redness stinging, burning or irritation, however, it normally disappears when discontinuing the use of the patches.

## **Dosage and Administration**

1. Wash your hands and the scar area with soap and water. Dry thoroughly.
2. Cut the patch to fit the scar area so that the edges of the gel patch extend at least 1/4" beyond the scar on all sides.
3. Peel of the strip and place the sticky side of the patch directly onto the scar or wound. Leave on for 8-12 hours per day then remove. Do not discard the mylar release strip.
4. When not wearing the patch, place the patch back onto the mylar release strip.
5. Discard the patch and replace with a new patch every 5 - 7 days.

## **How Supplied**

Polytoza is supplied in:

Cartons containing 4 Patches packed in individual envelopes containing 1 patch each (5cmx14cm),  
NDC 69336-804-04

## **Storage:**

Storage: Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Protect from light and moisture.

## **Distributed By:**

Sterling-Knight Pharmaceuticals, LLC  
Ripley, MS 38663  
Rev 0718-1  
Product Code: 804

## **PRINCIPAL DISPLAY PANEL**

Sterling-Knight Pharmaceuticals, LLC  
Ripley, MS 38663  
Rev 0718-1  
Product Code: 804

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 Silicone Gel Patch 100%  
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## POLYTOZA

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### Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRC:69336-804
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-804-04	4 in 1 PACKAGE		
1		1 in 1 POUCH; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K083718	02/12/2020	

**Labeler** - Sterling-Knight Pharmaceuticals, LLC (079556942)

## Establishment

Name	Address	ID/FEI	Business Operations
Sterling-Knight Pharmaceuticals, LLC		079556942	manufacture, label

Revised: 2/2020

Sterling-Knight Pharmaceuticals, LLC