

**NUVAGEL- elastomer, silicone, for scar management**  
**PureTek Corporation**

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**Nuvagel™**

**Rx Only**

For external use only

**Description**

**Nuvagel™** is a Silicone Gel Scar Dressing™ which is soft, comfortable, self-adhesive and Reusable.

**Nuvagel™** flattens, softens and fades both existing and new hypertrophic scars or keloids.

**Indications and Usage**

For non-invasive management of both existing and new hypertrophic scars or keloids.

**Use under the direction of a medical practitioner.**

**Contraindications:**

**Nuvagel™** is contraindicated for patients with sensitivity to silicone.

**Warnings and Precautions:**

For external use only.

- 1) Stop use, in case of itching, blisters, or skin irritation.
- 2) Do not apply to the surgical wound until at least 1 week after suture removal.
- 3) Skin surface must be cleaned before use. Using this product on uncleaned skin surface or applying it with excessive tightness may result in roseola (rash).
- 4) Product can be reused. If adhesive side is dirty, rinse with warm water and allow to be dried before reapplying .
- 5) The **Nuvagel™** Silicone Gel Scar Dressing should not be shared with other individuals.
- 6) Do not use on unhealed or open wounds.

**Keep out of direct sunlight and Under 40°C (104 °F).**

**Storage time above these conditions should not exceed 18 hours.**

**Dosage & Administration:**

**Important:**

Apply the **Nuvagel™** Silicone Gel Scar Dressing to the skin for 4-8 hours to ensure no adverse reactions occur. Once a trial application is completed without adverse reaction, the **Nuvagel™** Silicone Gel Scar Dressing may be applied to clean skin nightly before bed and removed each morning. Most treatment period will last for two months. In case of serious skin conditions, continue using for 3-6 months or as directed by your physician.

**How to use:**

1. Open pouch and remove **Nuvagel™** Silicone Gel Scar Dressing.
2. Cut the sheet to the size and shape of the affected skin area. If the skin area is larger, several sheets may be applied with edges aligned.
3. Remove the plastic film from the back of the sheet carefully and place the adhesive side onto clean skin. With good extensibility, it won't tend to fall off. However, during sleeping or doing a lot of exercise, you can use a thin flex yarn tape or an adhesive tape to keep it in place.
4. Replace the sheet weekly or when it is no longer secure on the skin.

**How Supplied:**

**Nuvagel™** is provided in a shipping pouch containing three (3) individually wrapped pouches. Each pouch contains one **Nuvagel™** 10 cm x 12 cm pad.

**Storage and Handling:**

Keep out of direct sunlight and under 40°C (104°F).

Storage time above these conditions should not exceed 18 hours.

**Adverse Reactions:**

In rare circumstances, use of **Nuvagel™** may cause skin irritations including redness, stinging or other irritations. Those effects should go away after use of **Nuvagel™** is discontinued.

**Manufacturer:**

**Nuvagel™** is manufactured by:

Hudson Scientific LLC  
103 W. Main St.  
Hudson, MI 49247

Rx Only

**Nuvazil™ Pouch Label**

The label on each pouch containing a **Nuvazil™** sheet is pictured below:

Nuvazil™

# Silicone Gel Scar Dressing

Soft, Comfortable, Self-adhesive and  
Reusable.

Flattens, softens and fades both existing and  
new hypertrophic scars or keloids.

1 PC

10 cm x 12 cm

LOT



See carton for directions for use.

Manufactured by:  
Hudson Scientific  
Hudson, MI 49247  
For questions or information  
call: 517-212-4047

50097 Rev A

## Nuvagel™

Packaged for :

### **PureTek Corporation**

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

**IMPORTANT:**

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- 1) Open pouch and remove Nuvagel™ Silicone Gel Scar Dressing.
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- 4) Replace the sheet weekly or when it is no longer secure on the skin.

**Cautions:**

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Packaged for :  
**PureTek Corporation**  
Panorama City, CA 91402  
For questions or information  
call toll-free: **877-921-7873**  
List No.78150IAA Rev. 38292



Lot:                      Exp:

NHRIC 59088-781-50

**Rx Only**

**Nuvagel™**

**Silicone Gel Scar Dressings**

**3 Sheets  
10 cm x 12 cm**

**Keep out of direct sunlight and Under 40 °C (104 °F).  
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**Use under the direction of a medical practitioner**

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Panorama City, CA 91402  
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List No. 78150IAA Rev. 38291



# NUVAGEL

elastomer, silicone, for scar management

## Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:59088-781
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:59088-781-50	3 in 1 POUCH		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	MDA	04/09/2021	

Revised: 4/2021

PureTek Corporation