

## **PROTEZALL- elastomer, silicone, for scar management**

### **V2 Pharma**

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### **Protezall medium silicone gel sheets for scars**

#### **Description**

Protezall is a Silicone Gel Scar Dressing which fades and softens existing scars, as well as new hypertrophic keloids or scars. Protezall is very comfortable to wear, reusable and washable. Each of the enclosed sheets can last up to eight days with proper care.

#### **Indications and Usage**

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

#### **Contraindications:**

Protezall is contraindicated for patients who are sensitive to silicone.

#### **Warnings and Precautions:**

For external use only.

Stop use in the event of itching, blisters, or skin irritation.

Do not apply to the surgical wound until at least 1 week after sutures, if any, have been removed. Do not use on open or unhealed wounds.

Clean skin surface before use. A rash may result if the skin surface has not been cleaned.

Each gel sheet can be reused for up to eight days. If adhesive side is dirty, wash it gently with a finger using antibacterial soap and water. Rinse gently and allow the sheet to dry.

Protezall should not be shared with others.

#### **Dosage & Administration:**

##### **Instructions for use:**

1. Prior to use, wash hands and area of application. Dry thoroughly.
2. Open the non-sterile pouch containing the Protezall Gel Sheeting
3. The gel sheet is covered on its "sticky" side by a plastic film. Remove the gel sheeting from the mylar release strip prior to use.
4. The gel sheet may be cut into smaller pieces using scissors. Once you have determined the appropriate size of sheeting to use, apply sticky side to the area. The gel sheeting should fully cover the area.
5. Place the sticky side of the gel sheet directly onto the scar. For best results, wear the gel sheet 8-12 hours per treatment. Wait 8-12 hours without use before next

treatment.

6. Gel sheet is reusable. When not wearing the gel sheet, place the gel sheet (sticky side) back onto the mylar release strip. Place the gel sheet back into the original pouch for protection.
7. When the sticky side of the gel sheet appears dirty or worn, use your finger to gently wash the gel sheet with anti-bacterial soap and water, as needed. Rinse with water and allow to air dry. The stickiness will return once dry. Do not fold while washing or drying.

### **How Supplied:**

Protezall is provided in a box containing four individually wrapped pouches, each containing one Gel Sheet.

### **Storage and Handling:**

Store at 20-25C (68 to 77F). Keep away from heat and protect from freezing.

### **Adverse Reactions:**

Although very rare, Protezall may cause skin irritations including redness, stinging or other irritations. Those effects should go away after use is discontinued.

### **Manufacturer:**

Protezall is manufactured by Hudson Scientific LLC, Hudson Michigan for:

V2 Pharma LLC  
103 W. Main St.  
Hudson, MI 49247

### **Protezall Box**

Protezall is sold in a box resembling the following:



## PROTEZALL

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### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:72835-100
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC: 72835-100			

1	NHRC: 72833-100-00	4 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
exempt device	MDA		05/15/2023	

**Labeler - V2 Pharma (102457346)**

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
V2 Pharma		102457346	repack, relabel

Revised: 6/2023

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