

**SCARHEAL SCAR PATCH- elastomer, silicone, for scar management**  
**Forreal Pharmaceuticals LLC**

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**ScarHeal Scar Patch**

**INDICATIONS**

Gel Sheeting is intended for use in the management, control, and prevention of old and new hypertrophic or keloid scars resulting from burns or surgical or traumatic injury of the skin.

**CONTRAINDICATIONS**

Do not use on open wounds or when any Dermatological conditions disrupt the skin (such as a rash).

**HOW SUPPLIED**

Non-sterile product is labeled as such and supplied in a protective package within a protective outer container.

**WARNINGS, PRECAUTIONS, ADVERSE REACTIONS**

**Possible complications include:**

|  |   |
|--|---|
| <ul style="list-style-type: none"><li>• Superficial maceration of the skin</li></ul> | <ul style="list-style-type: none"><li>• Rash,</li></ul>     |
| <ul style="list-style-type: none"><li>• Skin Discoloration</li></ul>                 | <ul style="list-style-type: none"><li>• Pruritus,</li></ul> |
| <ul style="list-style-type: none"><li>• Sheeting tack and thickness vary</li></ul>   |   |

Rashes have been observed on skin under the gel sheeting, this has been attributed to poor or insufficient hygiene. Similar rashes have been attributed to gel sheeting being wrapped too tightly. Should a rash occur, stop using the gel sheeting for 12 hours followed by using the gel sheeting for 12 hours. If the rash persists, a physician should be contacted, and gel sheeting use should be discontinued.

Discoloration of the skin covered by silicone gel sheeting has been reported, particularly in dark skinned patients. This effect appears to be transient and may be similar to the discoloration experienced whenever an area of skin is covered for extended periods of time.

Some patients report differences in gel sheeting surface tack and thickness from sheet to sheet. Perception of tack is subjective and the adhesive characteristic of gel sheeting may vary. These variations do not affect the function of the product.

Small bubbles may form after repeated washing and use. This does not have an impact on the function of the product.

Do not use creams, lotions, sun block or other silicone products on your skin when wearing silicone gel sheeting. These products will create a barrier between the scar site and silicone gel, preventing a proper healing environment.

For children under 5 years of age, use under adult supervision.

**INSTRUCTIONS FOR USE**

**Silicone Gel Sheeting**

1. Wash both scar and hands per cleaning instructions.
2. Open the non-sterile pouch containing the Silicone Gel Sheet.
3. Clear gel sheeting is covered on both sides by a plastic film. Fabric gel sheeting is covered on the tacky side by a plastic film. Remove plastic film prior to use.
4. The gel sheet may be cut into smaller pieces using scissors or a scalpel. Once you have determined the appropriate size of sheeting to use, apply tacky side to the scar. The gel sheeting should fully cover the scar and extend ¼ inch all the way around the scar border.
5. The exposed surface of the gel sheeting may be covered with surgical tape or bandage to help hold in place and to prevent sticking to other surfaces.
6. If the product is worn during sleep, it should be secured. Use of medical tape (Epi-Tape) or other means is recommended to keep the product from falling off.

**CLEANING INSTRUCTIONS**

Remove the gel sheet every 12 hours to wash both the scar and the gel sheet. In a basin of warm water, work

up a small amount of lather with the soap. Gently wash the piece of gel sheeting in the soapy water, rinse, and then air dry. Make sure the sheeting is completely dry before re-applying to the scar. After washing, rinsing, and drying the scar site re-apply the piece of gel sheeting.

## **WEARING TIME**

Optimal wearing time for silicone gel sheeting is 24 hours per day.

If it is not possible to wear the gel sheet for the recommended 24-hour period, a minimum of 12 hours per day is required, washing per the instructions above once in that period. Follow this procedure each day, washing and re-applying the gel sheeting to the scar for 1 to 2 weeks. At that time the piece of gel sheeting will begin to lose its adhesive quality and/or may become embedded with surface dirt. When this occurs, discard the piece of gel sheeting, and apply a new piece.

The overall optimal period of use is usually 8 to 12 weeks.

Incident Notice: Any serious incident that has occurred in relation to this product should be reported to and the competent authority of the Member State in which the user and/or patient is established.

## **Product Label**

**NDC: 81877-600-04**

**Rx Only**

**ScarHeal**

**Scar Patch**

***Silicone Gel Sheet***

**4-Silicone Gel Sheets**

*(2) 2" X 2.5" pouches per pack - 2 Packs*  
(Non-sterile)

**Siladone Gel Sheeting is intended for use in the management, control and prevention of old and new hypertrophic or keloid scars resulting from burns or surgical or traumatic injury of the skin.**

**Do not use on open wounds or when any Dermatological conditions disrupt the skin (such as a rash).**

**See enclosed insert(s) for full prescribing information.**

## **INSTRUCTIONS FOR USE**

### **ScarHeal Gel Sheeting**

1. Wash both scar and hands per cleaning instructions.
2. Open the non-sterile pouch containing the Silicone Gel Sheet.
3. Clear gel sheeting is covered on both sides by a plastic film. Fabric gel sheeting is covered on the tacky side by a plastic film. Remove plastic film prior to use.
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6. If the product is worn during sleep, it should be secured. Use of medical tape (Epi-Tape) or other means is recommended to keep the product from falling off.

Packaged For:

Forreal Pharmaceuticals LLC

Royal Oak, MI 48067

**Questions or Comments please call 877-367-3250**

## **SCARHEAL SCAR PATCH**

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**Product Information**

|                     |                |                           |                 |
|---------------------|----------------|---------------------------|-----------------|
| <b>Product Type</b> | MEDICAL DEVICE | <b>Item Code (Source)</b> | NHRIC:81877-600 |
|---------------------|----------------|---------------------------|-----------------|

**Packaging**

| # | Item Code          | Package Description  | Marketing Start Date | Marketing End Date |
|---|--------------------|--|----------------------|--------------------|
| 1 | NHRIC:81877-600-04 | 4 in 1 BOX   |                      |                    |
| 1 |                    | 1 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug |                      |                    |

**Marketing Information**

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| premarket notification | K003948                                  | 06/03/2022           |                    |

**Labeler** - Forreal Pharmaceuticals LLC (118029197)

Revised: 6/2022

Forreal Pharmaceuticals LLC