**SILATRIX ORAL- oral wound dressing gel**
**SA3, LLC**

---

**Silatrix Oral Gel**

**SILATRIX ORAL GEL**
**SA3, LLC**
**----------**

**SILATRIX ORAL GEL**
**Rx only**
**For oral mucosa area only**
**Not for ophthalmic use**

## DESCRIPTION

**SILATRIX ORAL GEL** is an amorphous hydrogel formed by the controlled reaction of sucralfate with a limited quantity of malic acid and calcium carbonate solution. The amorphous hydrogel formed by this reaction binds reversibly to wounds and is intended to form a protective film that covers wounds, protects against further irritation and relieves pain.

Silatrix Oral Gel may be administered directly to an accessible oral wound to provide an adherent physical covering of the wound bed. Although prepared by reaction of sucralfate with an acid, the polymerized sucralfate self-buffers to a pH 5.0 - 7 .0.

## INGREDIENTS

**SILATRIX ORAL GEL** contains sucralfate, malic acid, calcium carbonate, calcium sulfate dihydrate, sucralose, xanthan gum, propylene glycol, and purified water.

## INDICATIONS AND USES

**SILATRIX ORAL GEL** forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The oral gel may be used in the management of mouth lesions including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery.

## CONTRAINDICATIONS

**SILATRIX ORAL GEL** is contraindicated in patients with known serious hypersensitivity to sucralfate or any of the listed ingredients.

## WARNINGS

For oral mucosa area only. Avoid direct contact with eyes.

**KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

## PRECAUTIONS

Stop use and ask a doctor if irritation develops. **SILATRIX ORAL GEL** has no known serious side effects or adverse reactions. 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 or other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

## DOSAGE AND ADMINISTRATION

Apply to mucosal wounds 2 to 3 times daily.

## HOW SILATRIX ORAL GEL IS SUPPLIED

**SILATRIX ORAL GEL** is supplied in:
10 gram (0.35 oz) tube
NDC: 69420-8351-1

## STORAGE:

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

Silatrix Oral Gel
Polymerized Sucralfate Gel 10%
(1 gm/10 gm)
10 gram (0.35 oz)
NDC: 69420-8351-1


# SILATRIX ORAL

oral wound dressing gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | MEDICAL DEVICE | **Item Code (Source)** | NHRIC:69420-8351 |
| **Route of Administration** | ORAL | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NHRIC:69420-8351-1 | 10 in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Premarket Notification | K202000 | 02/17/2021 | |

**Labeler -** SA3, LLC (079627454)

Revised: 1/2022 SA3, LLC