

Silicon Dioxide Gel 10g

1. Name of the medicinal product

Silicon Dioxide Gel 10g

2. Qualitative and quantitative composition

Each gram contains Silicon Dioxide Q.S.

For excipients, see 6.1.

3. Pharmaceutical form

Gel for topical application.

4. Clinical particulars

4.1 Therapeutic indications

Silicon Dioxide Gel is indicated in the management of closed hyperproliferative (hypertrophic or keloid) scars, resulting from general surgical procedures, trauma, wounds, and burns.

4.2 Posology and method of administration

Start treatment as soon as the wound is closed or stitches are removed. Ensure that the affected area is clean and dry.

Apply Silicon Dioxide Gel to the area as a very thin layer, do not rub in, but allow to dry. Remove any excess product if it does not dry completely. Once dry, sunblock and cosmetics can be applied.

Apply twice daily. For maximum effect, Silicon Dioxide Gel should have 24 hour contact with the skin.

Recommended minimum treatment is 60-90 days, older scars may take longer; continue to use if improvement is still seen after the initial 90 days.

Method of administration

- Ensure that the affected area is clean and dry.
- Wipe off any excess cream if you have been using cream to massage.
- Apply a very thin layer of gel, gently wiping over the scar twice to spread it evenly.
- Allow to dry for 4-5 minutes before putting on clothes or pressure garments.
- Once dry, you can apply cosmetics or sunblock on top of the gel.
- If it takes longer than 4-5 minutes to dry, you have used too much. Wipe off the excess and allow to dry.

4.3 Contraindications

Silicon Dioxide Gel is contra-indicated in subjects with known hypersensitivity to the product and its components.

4.4 Special warnings and precautions for use

Warnings

For external use only.

Avoid direct contact with eyes, lips or mucous membranes.

Do not apply on areas of broken skin.

Do not apply on third degree burns and open wounds.

Never use on sutured wound until sutures have been removed.

Do not use on dermatological conditions that disrupt the integrity of the skin.

Precautions

Stop use and ask a doctor if irritation develops. In rare instances, silicone gel may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the silicone gel 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.

This medication should be used as directed by your physician during pregnancy or while breastfeeding.

Consult your doctor about the risks and benefits.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known.

4.6 Pregnancy and lactation

The limited data available on the use of Silicon Dioxide Gel in pregnancy which provide no indication of any risk to the fetus.

It is not known whether Silicon Dioxide is excreted in human breast milk.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

On rare occasions, the gel may cause temporary redness, stinging, burning or irritation and normally disappear when the medication is discontinued.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly. By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

There are no reports of overdosage of Silicon Dioxide Gel.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Silicon Dioxide Gel is a clear, self-drying gel. Research has shown that silicone can help to reduce the colour, height and texture of a scar. Silicone can also relieve itching and discomfort from the scars.

The exact mechanism of action in improving the appearance of scar tissue from using silicone remains unknown. However, various suggestions have been made to explain the efficacy of silicone, 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 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 gel 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.

5.2 Pharmacokinetic properties

Not available.

5.3 Preclinical safety data

Not available.

6. Pharmaceutical particulars

6.1 List of excipients

Cyclopentasiloxane
Bis-Vinyl Dimethicone/Dimethicone Copolymer
Dimethiconol
Dimethicone
Cyclotetrasiloxane
Silicon Dioxide
Steraryl Alcohol

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C.

Silicon Dioxide Gel 10g - Summary of Product Characteristics (SmPC) -

Keep away from heat and protect from freezing.

Keep out of the reach of children.

6.5 Nature and contents of container

Composite tube with polypropylene cap. Contains 10g of gel.

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder

Maltobic Pharmaceutical Company Nigeria Limited

15, Orlu Street, Ipegge Onitsha, Anambra state, Nigeria