

Silicone Gel – Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Silicone Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10g of gel contains:

Polydimethylsiloxane (Dimethicone) – 0.85g

Cyclomethicone – 0.15g

Excipients – q.s to 1g

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Silicone Gel is a clear, transparent, and viscous gel. It is smooth in texture and spreads evenly over the skin. It is non-comedogenic, non-sticky, and forms a protective barrier on the skin.

4. Clinical particulars

4.1 Therapeutic indications

Silicone Gel is indicated for the management and prevention of hypertrophic and keloid scars resulting from surgeries, burns, trauma, and other injuries. It helps to flatten, soften, and smooth scars, relieve the itching and discomfort associated with scars, and reduce redness.

4.2 Posology and method of administration

Posology

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

Apply Silicone gel in 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, Silicone 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.

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4.3 Contraindications

Silicone gel is contra-indicated in subject with known hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Do not apply on broken or infected skin.

4.4 Special warnings and precautions for use

For external use only

Keep out of reach of children

Avoid direct contact with eyes, lips or mucous membranes

Do not apply on area 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, silicon 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 physicians. If ingested get medical help or contact poison control center right away

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 Silicone gel in pregnancy which provides no induction of any risk to the fetus.

It is not known whether Silicone gel is excreted in human breast milk.

4.7 Effects on ability to drive and use machines

Silicone gel has no or negligible influence on the ability to drive and use machines.

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

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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

No case of overdose has been reported.

Topical overdose is unlikely. In case of accidental ingestion, seek medical attention.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: ATC Code: D11AX

Silicone gel forms a protective barrier over scars, regulating collagen production, and improving scar texture, colour, and height. Silicone Gel is a clear, self-drying gel. Research has shown that silicon can help to reduce the colour, height and texture of a scar. Silicon can also relieve itching and discomfort from the scars. The exact mechanism of action in improving the appearance of scar tissue from using silicon remains unknown. However, various suggestions have been made to explain the efficacy of silicone, including hydration, pressure, temperature, oxygen transmission and silicone absorption. There are 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, vasodilation 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 if static electricity on silicone may influence the alignment of collagen deposition.

5.2 Pharmacokinetic properties

Not Available.

5.3 Preclinical safety data

Not Applicable.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cyclopentasiloxane
Bis-Vinyl Dimethicone copolymer
Dimethiconol
Dimethicone
Cyclotetrasiloxane
Silicon Dioxide
Stearyl Alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30⁰C
Keep away from heat and protect from freezing
Keep the tube tightly closed after use.

6.5 Nature and contents of container

Silicone Gel is available in 10 g, 15 g, and 20 g collapsible aluminum or laminated tubes packed in a carton with an enclosed leaflet.

6.6 Special precautions for disposal

No special requirements.

7. APPLICANT/MANUFACTURER

Chinare Ani Pharmaceuticals Ltd.
52-B Ishokun-Odo Street, Ijebu-Owo, Ondo State, Nigeria.

8. MANUFACTURED BY

Protech Biosystems Pvt. Ltd.
Khasra No. 251,252, Sisona-Bhagwanpur, Roorkee-247661, Distt. Haridwar, Uttarakhand, India.

9. MARKETING AUTHORISATION NUMBER(S)

Not Applicable.