

SPC-Summary of Product Characteristics

1. Name of the Medicinal Product

PRAICON (Silicon Dioxide Gel 10mg)

2. Qualitative and Quantitative Composition

Each gm Contains:

Silicon Dioxide USP 10mg

Gel Base Q.S.

For Excipients see point 6.1

3. Pharmaceutical Form

Topical Gel

4. Clinical Particulars

4.1 Therapeutic Indications

PRAICON is an anti-scar agent useful in effective scar management resulting from surgery, burns and other injuries. It is also helpful in the maintenance of skin moisture. It contains polydimethylsiloxane and silicon dioxide as active ingredients helps to disappear scars safely and effectively.

- Reduces scars resulting from surgery, burns and other injuries
- Maintains skin moisture

4.2 Posology and Method of Administration

Always apply PRAICON as directed by the doctor. It is for external use only. Wash the scar area and pat dry. Apply a very thin coat of PRAICON directly to the affected area/scar area. To maintain coverage, apply twice daily or as directed by the doctor. Avoid contact with eyes, mucous membranes and third degree burns.

4.3 Contraindications

Hypersensitivity

4.4 Special Warnings and Precautions for use

Polydimethylsiloxane and silicon dioxide heals scars by increasing hydration of skin and results in softer and flatter scar. It protects the scar tissue from bacterial invasion and also reduce itching and discomfort associated with scars.

Precautions

- Always apply PRAICON as directed by the doctor
- Apply twice daily or as directed by the doctor
- It is for external use only
- Wash the scar area and pat dry
- Apply a very thin coat of PRAICON directly to the affected area/scar area
- Avoid contact with eyes, mucous membranes and third degree burns
- Do not use on open wounds
- Do not apply if you are allergic to any of its ingredients
- Inform your doctor about your medicines that you use, including prescription, over-the-counter medications and herbal supplements

- Avoid the contact of PRAICON with the eyes. If accidentally it goes into the eyes, wash your eyes with the water. If irritation persists, consult a doctor.

4.5 Interactions with other medicinal products and other forms of interactions

None

4.6 Fertility, Pregnancy and Lactation

Silicon is commonly consumed in foods. There isn't enough reliable information to know if it's safe to use as medicine or what the side effects might be. Stay on the safe side and stick to food amounts.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable Effects

Consult your doctor if you notice any side effects while using PRAICON.

4.9 Overdose

Not applicable.

Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anti-scar agent

ATC code: CID 24261

5.2 Pharmacokinetics

In one study, the majority of silicon dioxide was rapidly cleared from circulation, and the excretion of radioactivity from intravenously dosed silicon dioxide was found in urine and feces

5.3 Pre-Clinical Safety Data

Not Available

6. Pharmaceutical Particulars

6.1 List of Excipients

Carbomer - 934
Sodium Methyl Paraben BP
Sodium Propyl Paraben BP
Isopropyl Alcohol BP
Propylene glycol BP
Tween 80 BP
Benzyl Alcohol BP
Purified Water BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months from the Date of Manufacture

6.4 Special precautions for Storage

Store in cool and dry place at temperature not exceeding 30°C. Protect from Light.

Do not freeze.

6.4 Nature and contents of Container

A printed carton containing a leaflet and a printed 15gm collapsible tube.

6.5 Special precautions for disposal

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements
Puncture nozzle seal with piercing point of cap, Re-place Cap tightly after use.

FOR EXTERNAL USE ONLY

5. Manufacturing Authorization Holder

Merit Organics Ltd.

Plot No 2104/2/A , G.I.D.C , Sarigam , Bhilad,

Dist Valsad-396155 Gujarat INDIA

6. Marketing Authorization Numbers

Praipec Pharmaceutical Ltd.

20B, Ikemba Road 1, Ogidi

Idemili LG, Anambra State.

7. Date of First Authorization/Renewal of Authorization

21.10.2024

8. Date of Revision of the text

Applicable once the registration is obtained