DESENSITIZER - SENSARA - SENSIGUARD

(Re-mineralizing & Desensitizing Gel)

INSTRUCTIONS FOR USE (Please read carefully before use)

Revision	01/01
Date	29.08.2026

Doc. No: **HH/IFU/07** Approved By: **Mr. Vikram Vora** Language: **English**

PRODUCT DESCRIPTION: Desensitizer is a re-mineralizing gel which reduces post-whitening sensitivity and effectively enhances the re-mineralization of the enamel. Potassium nitrate acts on the dentinal nerve to reduce sensitivity, while sodium fluoride promotes remineralization of demineralized enamel. Intended to be used as a remineralizing and de-sensitizing agent.

MATERIAL OF CONSTRUCTION: Potassium nitrate (desensitizing agent), sodium fluoride (remineralizing agent), glycerine, thickening agent.

INDICATIONS: Remineralization of de-mineralized tooth structure; post-whitening sensitivity; sensitivity caused due to non-carious lesions and sensitivity after oral prophylaxis.

INTENDED USE: Chairside application as a remineralizing and de-sensitizing agent, for use in dentistry by qualified dental personnel.

CONTACT TIME: Leave the gel undisturbed on the tooth surface for 10 to 15 minutes.

PROCEDURE & PRODUCT HANDLING: For chairside use by dental professionals only.

- Rinse the tooth surfaces and dry them with a cotton roll; avoid cold water or compressed air.
- Remove and set aside the cap from the 3 g syringe and affix a disposable dispensing tip; first-time use may require additional pressure on the plunger for the gel to appear at the tip.
- Immediately before use, express a small amount of gel from the syringe directly onto the tooth surfaces to be treated, or into a dappen dish or onto a mixing pad.
- Apply the gel over the sensitive surfaces in a thin, even layer with a cotton or foam pledget or microbrush applicator, covering the entire area under treatment; a rubbing/pumping motion encourages the gel to penetrate the surface. If the applicator dries out during use, re-wet it with more gel.
- Leave the gel undisturbed on the tooth surface for 10 to 15 minutes, then rinse off thoroughly.
- Repeat the application if sensitivity persists; if it persists after a second application, consider other possible sources of pain (e.g. high occlusion, pulpal pathology, extreme root erosion).
- Issue appropriate post-op instructions and dismiss the patient.
- Discard the applicator tip and recap the syringe to prevent drying out of the material.

CAUTION / WARNING:

1. Device to be used by a qualified dentist or dental technician only.
2. Avoid prolonged or repeated contact with skin (allergic contact dermatitis) and eyes. Avoid prolonged inhalation. Do not take internally.
3. Contact with the skin may cause irritation or burns of hypersensitivity.
4. It should not be used with patients who have a history of severe allergic reaction to any of the components.

PRECAUTIONS:

1. Avoid prolonged or repeated contact with skin and eyes; avoid prolonged inhalation; do not take internally.
2. Eye contact: if the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician.
3. Skin contact: if contact with skin occurs, immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs, discontinue use and seek medical attention.
4. The dispensed material shall not be placed back in the container and the dose once applied and used shall not be reused.

CONTRAINDICATIONS:

1. This product is contraindicated for use in or by individuals who have known hypersensitivity to any of the constituents of the product.

INTERACTIONS WITH OTHER DENTAL MATERIALS: Kindly communicate and inform the manufacturer with complete details in case of any incidences of interaction.

ADVERSE REACTIONS: No side effects when storage, transport and application instructions are observed. Kindly communicate and inform the manufacturer in details of any instance.

PACKAGING: Gel, 3 g syringe.

STORAGE CONDITIONS: Store at a temperature between 10°C and 30°C. Keep away from direct sunlight and moisture. Keep locked up and out of the reach of children. Close the cap carefully after use. Shelf life not affected after opening if stored in a cool dry place. Do not use after expiry date.

SHELF LIFE: 2 years from the date of manufacturing.

DISPOSAL: Dispose in accordance with local, state and federal environmental regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

LOT Symbol for "BATCH CODE"	Symbol for "USE BY"	Symbol for "NON STERILE"
Symbol for "KEEP DRY"	Symbol for "CAUTION"	Symbol for "CONSULT INSTRUCTIONS FOR USE"
REF Symbol for "CATALOGUE NUMBER"	Symbol for "KEEP OUT OF THE REACH OF CHILDREN"	Symbol for "MANUFACTURER"
Symbol for "DO NOT USE IF PACKAGE IS DAMAGED"	30°C 10°C Symbol for "TEMPERATURE LIMITATION"	Symbol for "KEEP AWAY FROM SUNLIGHT"
MD Symbol for "MEDICAL DEVICE"	IN Symbol for "COUNTRY OF MANUFACTURE"	

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Kindly retain the instructions for use & packaging box until the complete use of the product / expiry.

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.