

D Sens P (Instructions For Use) (Dentin Desensitizer)

PRODUCT DESCRIPTION:

D Sens P is a sustained release, 3-4% potassium nitrate and 0.11% weight by weight fluoride ion, sticky, viscous gel. D Sens P is made to be used in a custom tray.

COMPOSITION:

Potassium Nitrate, Glycerine, Sodium Fluoride

INDICATIONS:

D Sens P desensitizing gel provides a film-like varnish for sensitive teeth, sealing dentinal tubules of exposed dentin and other areas where post-operative sensitivity is a concern. The product is used either by a dental professional in the office or provided to the patient for home treatment of dentin sensitivity.

Procedure:

- Read and understand instructions before using or dispensing to the patient.
- Fabricate tray to meet patient's needs. If patient already has a custom tray, D Sens P may be applied in the same tray and same manner as bleaching gel.
- If sensitivity is localized, place gel in affected area(s) and a small amount in the molar region to hold tray in place.
- The length and number of times tray is worn depends on condition, patient and clinician. Recommended treatment times can range from 15 minutes to 1 hour.
- Tray should be removed at mealtimes. Immediately following tray removal, patient should brush and rinse teeth with water to remove all the remaining gel. DO NOT swallow solution during rinsing. Wash tray and store in a tray storage case. Fresh gel should be used with each application.
- Gel may be warmed before placing in tray to avoid thermal sensitivity.

Precautions:

- Keep desensitization product away from small children.
- This product is NOT for nighttime use.

- Do not use tobacco products or eat while using this product.
- Not intended for use by pregnant women.
- If any problems occur, discontinue treatment, and notify your dentist.
- Avoid contact of the device with skin and mucosa, avoid contact with eyes. Avoid inhalation of fumes. Do not take internally.
- **Eye contact:** if the product comes in contact with eye, it may cause irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
- **Skin Contact:** Avoid contact with skin or mucosa, it may cause skin sensitization. If contact with skin occurs immediately wipe off thoroughly with cotton and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.
- Wear suitable gloves and protective glasses to avoid accidental exposure to skin and eyes.
- Do not transfer the excess material back into the container to avoid contamination.
- Patient should not swallow large amounts of D Sens P. Excess material at insertion and residue upon removal should be brushed off and rinsed. DO NOT SWALLOW.

Packaging: Multi dose plastic dispensing syringe refill.

Storage conditions: Keep Away from Direct Sunlight. Keep locked up and out of the reach of children. Store at a temperature between 10°C to 40°C.

Shelf life: 4 years from the date of manufacturing

Disposal Conditions: 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.

Manufactured by:

Shiva Products

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These instructions for use should be kept for the duration of product use.

- [LOT] Symbol for "BATCH CODE" [M] Symbol for "DATE OF MANUFACTURE" [H] Symbol for "USE BY" [NS] Symbol for "NON STERILE"
- [☀] Symbol for "KEEP DRY" [⚠] Symbol for "CAUTION" [I] Symbol for "CONSULT INSTRUCTION FOR USE"
- [REF] Symbol for "CATALOGUE NUMBER" [X] Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
- [👶] Symbol for "KEEP OUT OF THE REACH OF CHILDREN" [🏠] Symbol for "MANUFACTURER NAME & ADDRESS"
- [10°C/50°C] Symbol for "TEMPERATURE LIMITATION" [☀] Symbol for "KEEP AWAY FROM SUNLIGHT"

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.