Dentsply Sirona

Hemoban™ Gel

25% Aluminum Chloride Hemostatic Solution

DIRECTIONS FOR USE – ENGLISH
For dental use only.
USA: Rx only.

1. PRODUCT DESCRIPTION

Hemoban Gel is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle. Hemoban Gel leaves no residue or stain.

1.1 INDICATIONS

Hemoban Gel is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or Infusor Tip. The gel facilitates the insertion of the cord into the sulcus.

1.2 CONTRAINDICATIONS

None known.

1.3 COMPOSITION

Water, Aluminum Chloride, Sodium Borate
Hemoban Gel contains no epinephrine.

1.4 Delivery Forms

30mL syringe for filling individual, single-use treatment syringes
1.2 mL single-use (unfilled) syringes

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions for use.

CAUTION

Safety alert symbol
This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 WARNINGS

- Hemoban Gel contains aluminum chloride which may be irritating to skin and eyes. Use protective clothing and eye shield when loading and handling material.
- Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check.
- Do not use on patients with known allergies to aluminum chloride or chemical sensitivities.
- Do not allow product to be ingested
- Keep out of reach of children.

2.2 PRECAUTIONS

- This product is intended to be used only as specifically outlined in the Directions For Use. Any use of this product inconsistent with the Directions For Use is at the discretion and sole responsibility of the practitioner.
- Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- All syringe tips and empty syringes are disposable product and for single use only to avoid cross-contamination. Fill a new empty syringe with the amount of material needed for the individual patient. Dispose of syringe after use.
- The 30mL syringes cannot be reprocessed. To prevent syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe is handled offside the dental unit with clean/disinfected gloves. During treatment clinicians with patient contact should not handle 30mL syringes. Discard devices if contaminated.
- As additional precautionary measure, 30mL syringes may be protected from gross debris but not from all contamination by applying a protective barrier.
- Do not combine with other hemostatic agents or chemistries without first thoroughly cleansing tooth and surrounding tissue.
- Hemoban Gel is designed for intraoral use.
- Tightly close syringes with original cap immediately after use.
- Use only recommended tips.
- **Interactions**
  - Hemoban Gel, temporary cements, mucins, and blood will prevent quality adhesion and polymerization/set of resins and will lead to microleakage under any restoration. Preparations must be thoroughly cleaned using a firm air/water spray and/or pumice.
  - Hemoban Gel must be thoroughly washed from the preparation site with a firm air/water spray to avoid reaction with polyether materials and thereby compromising the surface set of the impression.
  - When using self-etch bonding agents, the tooth/preparation surface must be scoured with pumice and thoroughly washed before application. This is not necessary when using a phosphoric etch bonding system or when using conventional glass ionomer, zinc phosphate, or similar cements.
  - Do not combine with other hemostatic agents or chemistries without first thoroughly cleansing tooth and surrounding tissue.

2.3 Storage

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product. Keep out of direct sunlight and store in a well ventilated place at temperatures between 18°-29°C/65°-85°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

3. STEP-BY-STEP INSTRUCTIONS

3.1. General Procedures

Loading single-use syringe from 30mL Syringe

1. Select a clean, unused, single-use disposable 1.2 mL syringe. Use only syringes provided.

CAUTION

Cross-contamination - Infection
- Do not reuse single-use disposable syringe or dispensing tips.
- Do not attach used syringe to 30mL Syringe
- To prevent the syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the 30mL syringes are handled with clean/disinfected gloves. Do not reuse syringes if contaminated.

2. Away from the operating field, Remove Luer cap from 30mL syringe.
3. Attach a provided single-use disposable 1.2ml syringe to the male threads of the 30mL syringe.
4. Depress 30mL syringe plunger while guiding 1.2ml syringe plunger to desired fill.
5. Separate syringes and re-cap 30mL syringe. Note: If desired, place a small amount of Hemoban Gel from the 30mL syringe into a clean dappen dish or similar receptacle to soak cord prior to placement.
6. Securely attach Infusor Tip to 1.2 mL syringe.
7. Verify flow prior to applying intraorally. Material should flow freely with gentle pressure. DO NOT USE EXCESSIVE FORCE. If more than gentle pressure is required, remove from patient field and check for obstruction.

3.2 Impressions:

1. Follow "General" steps above.
2. Rub the Infusor tip around the full circumference of the preparation while expressing the solution into bleeding tissue surface to control bleeding.
3. Fill sulcus with hemostatic solution.
4. Displace tissue by packing size appropriate unsoaked retraction cord into sulcus. Optionally place a small amount of Hemoban Gel in a dappen dish and soak cord prior to packing.
5. Wait 1-3 minutes for retraction and hemostasis before removing cord.
6. Remove retraction cord. Use a firm air/water spray to clean preparation. Check for hemostasis. If bleeding occurs, repeat step 2 above to bleeding area. Re-check with air/water spray until bleeding has stopped.
7. Make impression following impression material manufacturer's directions for use.

3.3 Direct and Indirect Bonded Restorations:

1. Follow "General" steps above.
2. Lightly rub around the full circumference of the preparation expressing the solution into bleeding tissue surface to control bleeding.
3. After approximately 1-3 minutes, when hemostasis is obtained, use a firm air/water spray to clean preparation. Check for hemostasis. If bleeding occurs, repeat step 2 above to bleeding area. Re-check with air/water spray until bleeding has stopped.
4. Gently pack size appropriate cord into sulcus if desired
5. Wait 1-3 minutes and remove cord. If using an unsoaked cord for tissue displacement, cord may be left in place during restorative procedure to protect soft tissue or may be removed.
6. Rinse again with a firm air/water spray and dry.
7. Apply bonding agent and restorative as per manufacturer's instructions.

CAUTION

Contamination - Compromised adhesion
- The tooth and surrounding tissue should be thoroughly cleaned and all residual hemostatic agent and coagulum removed to avoid contamination of the dentin and/ or enamel substrate.
- Temporary cements may also contaminate the surface causing microleakage and bonding failure.
- Failure to do so may jeopardize the bond and seal causing microleakage.

4. HYGIENE

CAUTION

Cross-contamination. - Infection.
- Do not reuse single use products. Dispose of in accordance with local regulations.
- Syringe cannot be reprocessed. Dispose of contaminated syringe in accordance with local regulations.

4.1 Syringes – cross-contamination

CAUTION

Cross-contamination. - Infection.
- The 30mL syringes cannot be reprocessed.
- To prevent the syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the 30mL syringes are handled with clean/disinfected gloves. Do not reuse syringes if contaminated.
- During treatment clinicians with patient contact should not handle the 30mL syringe
- Dispose of contaminated syringes in accordance with local regulations.

To prevent 30mL syringes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended. The use of protective barriers is an additional precautionary measure against gross debris but not against all contamination. Incidental contact of the 30mL syringe with water, soap or a water-based hospital-level disinfection solution will not damage syringe body. Do not allow any solution contact with contained material. Discard material that has been in contact with any fluid or non-sterile instrument. Repeated liquid contact may damage label. Dry the 30mL syringe with a lint-free single-use cloth.
NOTE: Vigorous wiping can destroy the label. Wipe syringe gently. Dispose of residual material and empty syringes in accordance with local regulations.

5. LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "YYYY-MM" or "YYYY-MM-DD"
2. The following numbers should be quoted in all correspondence:
   - Reorder Number
   - Lot number
   - Expiration date

Manufactured for:
Dentsply LLC
38 West Clarke Avenue
Milford, DE 19963 USA
Tel.: 1-302-422-4511
www.dentsplysirona.com

Dentsply Sirona

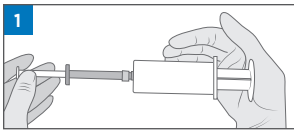
Hemoban™ Gel

25% Aluminum Chloride Hemostatic Solution

Rx Only — For Dental Use Only. Caution, consult instructions for use.

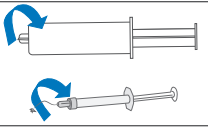
Technique Guide

1



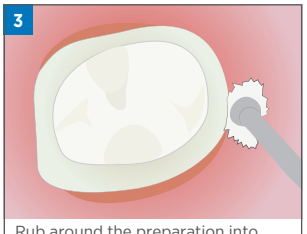
Remove cap from 30mL syringe and attach a 1.2mL syringe to the male threads of the 30mL bulk dispensing syringe. Depress plunger to fill 1.2 mL syringe to desired level.

2



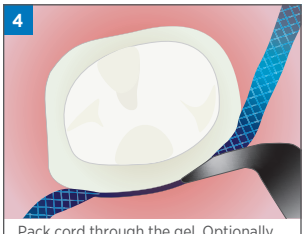
Separate syringes. Re-cap 30mL syringe. Securely attach Infusor Tip on 1.2 mL syringe. Verify flow.

3



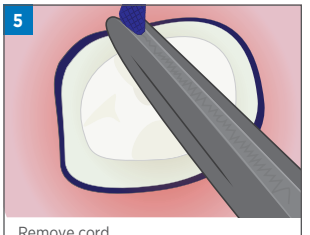
Rub around the preparation into bleeding tissue. Check for hemostasis. Fill sulcus with solution.

4



Pack cord through the gel. Optionally cord can be soaked in solution prior to packing. Wait for 1-3min.

5



Remove cord.
Rinse with air/water spray and dry.
Check for hemostasis.

6

Make final impression.