

UltraCal™ XS Calcium Hydroxide Paste

EN

Product Description

UltraCal XS calcium hydroxide paste is an aqueous, 12.0 to 12.5 pH, radiopaque, premixed paste for direct application.

For all products described, carefully read and understand all instructions and SDS information prior to use.

Delivery Form(s)

- 1.2 ml delivery syringe
- Required delivery tip
 - For intracanal application use NaviTip™ 29 ga Sideport Tip
 - For Vital Pulp Therapy application, use Micro 20 ga Tip

Indications for Use/Intended Purpose

UltraCal XS calcium hydroxide paste is indicated to be used as:

- Temporary dressing for root canals
- Apexification and/or perforation
- Vital Pulpotomy
- Direct Pulp Capping
- Indirect Pulp Capping
- Root resorption
- Root canal filling for primary teeth

Contraindications

- Do not use on patients with a known allergy to any of the formula contents
- Do not use outside of the tooth
- UltraCal XS paste can cause permanent paralysis when expressed into the inferior alveolar canal space. Proceed with caution when using UltraCal XS paste close to this anatomical area.
- UltraCal XS paste is not indicated to be expressed to the periapical tissue or inside a periapical lesion. Proceed with caution if the root canal is communicated with the inferior alveolar canal or maxillary sinus. If the clinician deems this treatment necessary, refer to the Warnings and Precautions section.

• For patients or users with allergy concerns, refer to product allergen document available at www.ultradent.com. If allergic reaction is observed, rinse exposed area thoroughly with water and have the patient consult their physician.

Warnings and Precautions

- Dental professionals must wear protective gloves and eyewear with side shields.
- Patient must wear eyewear with side shields.
- Take extra precaution to avoid UltraCal XS paste extrusion when working in locations with sensitive anatomical proximities—such as the inferior alveolar canal, mental foramen, maxillary sinuses, etc.
- Take extra precaution to avoid UltraCal XS paste extrusion when identifying root anatomical changes—such as root resorptions, wide opening foramen, incomplete root constriction, etc.
- Always verify that the tip is properly attached to the syringe before applying UltraCal XS paste
- Always verify the flow of UltraCal XS paste prior to expressing it intraorally
- The rubber stopper on the NaviTip 29 ga Sideport Tip is custom fit to the cannula. Ensure that the rubber stopper is at the predetermined length of 3–4 mm shy of the apex before inserting the tip into the canal. Verify the position of the stopper before each reinsertion into the canal.
- Do not express UltraCal XS paste if the NaviTip 29 ga Sideport Tip is wedged or bound inside the canal. The cannula must be kept loose in the canal.
- Monitor very closely the amount of UltraCal XS paste dispensed inside each canal to prevent overfilling of the canal. Only a very small amount of UltraCal XS paste is needed to fill a canal. If a small puff is noticed on the periapical X-ray, this quantity is usually tolerated very well by the surrounding tissue. However, UltraCal XS paste has a neurotoxic effect on the nerve. If UltraCal XS paste is expressed into the mandibular canal or maxillary sinus cavity, immediately refer to an oral surgeon for evaluation.
- Never express UltraCal XS paste into the periapical tissue or a periapical lesion. Extra precaution must be taken if the root canal is communicating with inferior alveolar canal or maxillary sinus.
- Do not use Capillary tips or any other plastic type tip for the delivery of UltraCal XS paste
- Avoid contact with skin, eyes, oral mucosa, soft tissue, etc., as UltraCal XS paste has a very high pH and can cause burns. In cases of contact, rinse immediately with copious amounts of water and seek proper medical attention.
- If swallowed: immediately rinse out mouth, then drink copious amounts of water, and seek proper medical attention
- Contact with saliva, blood, and other bodily fluids during application may reduce the efficacy of the UltraCal XS paste
- To avoid clogging of the tip, remove each tip and re-cap with Luer Lock Caps between each use
- Ensure that the tooth is properly isolated using a rubber dam
- Tips are single use only
- Use only required tips

Stepwise Instructions

Preparation

- 1) Follow instrumentation to the necessary apical enlargement. Clean and dry the canal.
- 2) Irrigate the canal with sterile water to remove any previously applied chemicals and any other debris in the area. Use a Luer Vacuum Adapter with Capillary tip to remove liquids. Dry the canal with paper points.
- 3) Use an apex locator with the last instrument used in the instrumentation to verify the working length
- 4) Remove Luer Lock cap from UltraCal XS paste syringe. Attach the required delivery tip (procedure-dependent) and verify the consistency of the flow before expressing intraorally. While slowly dispensing UltraCal XS paste, carefully evaluate the rate of expression to determine the quantity of UltraCal XS paste in the canal. If resistance in dispensing UltraCal XS paste is met, promptly replace the tip and verify the flow.

Use - Temporary Dressing for Root Canals, Root Resorption, Root Perforations, and Apexification

NOTE: Even when using a NaviTip 29 ga Sideport Tip, take extra precautions to avoid overfilling the canal.

- 1) Ensure that the rubber stopper is at the predetermined length of 3–4 mm shy of the apex before inserting the tip into the canal. Verify the position of the stopper before each reinsertion into the canal.
- 2) Only deliver with the NaviTip 29 ga Sideport Tip, staying at least 3–4 mm shy of the working length. Always keep the delivery tip loose in the canal. A rubber stopper mounted on the NaviTip 29 ga Sideport Tip assists in the precise and controlled placement of UltraCal XS paste into the root canal. To avoid expressing UltraCal XS paste beyond the foramen, DO NOT force the NaviTip 29 ga Sideport Tip or UltraCal XS paste into the canal. Make sure the cannula is not bound inside the canal. Gently and carefully deliver UltraCal XS paste inside the canal while slowly withdrawing the tip from the canal. STOP filling the canal if you notice

UltraCal XS paste has reached the coronal pulp chamber. If UltraCal XS paste is not visible at the canal entrance after 2 seconds of delivery, remove the tip and take an X-ray to verify the placement.

- 3) After dispensing UltraCal XS paste, take an X-ray to verify that the UltraCal XS paste has adequately filled the canal and not extruded past the apex. In the event UltraCal XS paste is extruded past the apex, refer to Warnings and Precautions.
- 4) Remove any excess UltraCal XS paste from the pulp chamber. Place a cotton pellet, sponge, or teflon in the pulp chamber. Seal the coronal opening with your preferred cement.
- 5) UltraCal XS paste should remain in the canal for 1–3 weeks to achieve optimal performance
- 6) After 2–3 weeks, UltraCal XS paste will start to be solubilized in the canal. If replacement is needed, repeat steps 1–5.
- 7) When removing UltraCal XS paste, use Citric Acid 20% with NaviTip™ FX™ Tip. Rinse the area again with sterile water. Use a Luer Vacuum Adaptor with Capillary tip to remove the liquid and dry the canal with paper points.
- 8) For Apexification: Repeat steps 1–7, changing UltraCal XS paste every 4 weeks. Do not exceed treatment beyond 6 months. If the apical closure is not achieved after 6 months, then perform an apical plug using desired repair cement.
- 9) For Perforation: Repeat steps 1–7 as necessary, changing UltraCal XS paste every 4 weeks until there is no internal bleeding or exudate when UltraCal XS paste is removed.
- 10) For final canal obturation, follow the instructions of your preferred endodontic sealing system

Use - Temporary Dressing for Root Canals in Non-Vital Primary Dentition

NOTE: Even when using a NaviTip 29 ga Sideport Tip take extra precautions to avoid overfilling the canal.

- 1) Ensure the rubber stopper is at the predetermined length of 3–4 mm shy of the apex before inserting the tip into the canal. Check the position of the stopper before each reinsertion into the canal.
- 2) Only deliver with NaviTip 29 ga Sideport Tip, staying at least 3–4 mm shy of the working length, always keeping the delivery tip loose in the canal. A rubber stopper mounted on the NaviTip 29 ga Sideport Tip assists in the precise and controlled placement of UltraCal XS paste into the root canal. To avoid expressing UltraCal XS paste beyond the foramen, DO NOT force the NaviTip 29 ga Sideport Tip or material into the canal. Make sure the cannula is not bound inside the canal. Gently and carefully deliver UltraCal XS paste inside the canal while slowly withdrawing the tip from the canal. STOP filling the canal if you notice UltraCal XS paste has reached the coronal pulp chamber. If UltraCal XS paste is not visible at the canal entrance after 2 seconds of delivery, remove the tip and take an X-ray to verify placement. Verify the length of each canal as they will vary due to the exfoliation process.
- 3) After dispensing UltraCal XS paste, take an X-ray to verify that the UltraCal XS paste has adequately filled the canal and not extruded past the apex. In the event UltraCal XS paste is extruded past the apex, refer to Warnings and Precautions.
- 4) Remove any excess UltraCal XS paste from the pulp chamber. Apply a thin layer of Ultra-Blend™ plus calcium hydroxide liner, ensuring that the Ultra-Blend plus liner covers the UltraCal XS paste and overlaps onto the surrounding dentin. Light cure the Ultra-Blend plus liner. This will prevent washout during the bonding procedure. Restore with your preferred restoration procedures.
- 5) Perform follow-up as necessary to ensure that the root exfoliation process is occurring concomitantly with the UltraCal XS paste solubilization.
- 6) If replacement is needed, repeat steps 1-5.

Use - Vital Pulpotomy, Direct and Indirect Pulp Capping, or Pulpal Floor Perforation

- 1) Ensure that the tooth is properly isolated to avoid contamination
- 2) Ensure that there is no intense bleeding. Apply Seconsep™ solution to the exposed areas and air dry.
- 3) Apply UltraCal XS paste gently on the exposed area. Do not dispense UltraCal XS paste into the coronal pulp chamber (Vital Pulpotomy, Direct and Indirect Pulp Capping). Apply a thin layer of Ultra-Blend plus calcium hydroxide liner, ensuring that the Ultra-Blend plus liner covers the UltraCal XS paste and overlaps onto the surrounding dentin. Light cure the Ultra-Blend plus liner. This will prevent washout during the bonding procedure. Restore with your preferred restoration procedures.

Processing

To avoid cross-contamination, wipe syringe with an intermediate level disinfectant between uses and use a disposable barrier sleeve. If a barrier sleeve is not used, syringe should be treated as single-use.

Storage and Disposal

Dispose of waste according to local rules, guidelines, and regulations.

Miscellaneous Information

Report any serious incident to the manufacturer and the competent authority. www.ultradent.com / 1-800-552-5512 / 801-572-4200

UltraCal™ XS Calcium Hydroxide Paste

Manufactured by
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Manufactured in the USA from globally sourced materials

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Rx Only

2°C
36°F

27°C
81°F