

MD

AHL Generic **HEMOSTATIC GINGIVAL RETRACTION PASTE****DIRECTIONS FOR USE****FEATURES:**

An astringent formulated to provide gingival retraction and hemostasis. Syringe contains an astringent retraction paste for any situation in which a temporary displacement of the marginal gingiva and/or the assurance of a dry and clean sulcus is required. The acidic paste containing aluminium chloride is applied from syringe tip into the sulcus. A hemostatic effect results from the compression on the gums by the paste containing aluminium chloride as an astringent. This hemostatic effect quickly closes any small blood vessels which might be unintentionally opened. Depending on the clinical situation and working technique of the person performing the treatment, the paste can be used as an alternative to or in combination with retraction cords or other retraction methods.

INTENDED PURPOSE:

Gingival retraction and hemostasis

INTENDED PATIENT POPULATION:

From child to geriatrics

INTENDED USER:

This product has been formulated for use in dentistry and is intended for use by dental professionals only.

CLINICAL BENEFIT:

Aid in taking impressions and cavity preparation.

INDICATIONS FOR USE:

It is intended for use prior to:

- Taking an impression.
- Cementation.
- Cavity preparation.

CONTRA-INDICATIONS:

- Do not use on persons with known allergy to aluminium chloride.
- Do not use in patients with significant periodontal disease or furcation involvement.

CONTENTS OF PACK:

2g Syringe x 2, disposable syringe tips x 12, Instructions for use.

PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- Do not insert cannula dispensing tip into the sulcus.
- Be sure all paste is removed before taking impression to avoid inhibition of polymerization of impression material.

PROCEDURE**(1) APPLICATION:**

- Remove the cap from the syringe.
- Be sure to retain cap for subsequent storage of the material.
- Place annealed luer dispensing tip onto end of the syringe tip, twist-lock into place.
- The soft tip allows for optimal access.
- Rinse and air dry prepared tooth.
- Extrude paste slowly into the sulcus while maintaining the dispensing tip just above the sulcus and aligned approximately parallel to the axial plane of the tooth preparation.

- Be careful not to jam dispensing tip into sulcus.
- Ensure you extrude sufficient material into the sulcus to achieve adequate tissue retraction.
- Allow gingival retraction paste to remain in the sulcus for at least one or two minutes.
- Often, the marginal gingiva will grow pale when retraction is achieved.
- After hemostasis has been achieved the paste should be removed by thoroughly rinsing using air-water syringe and saliva ejector or suction tip.
- Examine treatment site to verify complete removal of the paste prior to taking the impression.
- Remove syringe dispensing tip and dispose of properly after use.
- Re-cap syringe for storage in sealable foil bag.

SINGLE USE

The dispensing tip may only be used once due to hygienic reasons (prevention of cross-contamination between patients). Remove dispensing tip and dispose of properly after use. Re-cap paste syringe for storage in sealable foil bag – this may be used more than once.

STORAGE:

Store in a cool, dry place (5-25°C).

Always replace cap immediately after use.

EXPIRY:

The expiry date is shown in year, month format. Do not use the product after this date.

DISPOSAL:

Dispose of the contents and containers in accordance with relevant local and national requirements.

POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:

- This product contains substances that may cause an allergic reaction.

BATCH CODE:

The batch code gives an open date of manufacture in month, year, day format with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES:

394X1 2 x 2g Syringes + 12 Tips

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the above address stating the batch number shown on the packaging.

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental professional.



Advanced Healthcare Ltd., Tonbridge, Kent, TN11 8JU, UK
Tel: +44 1892 870500 Email:sales@ahl.uk.com



Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

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