Grace Medical
AN INNOVIA MEDICAL COMPANY

INSTRUCTIONS FOR USE

EPI-STOP™ NASAL GEL

READ ALL INSTRUCTIONS PRIOR TO USE

Device Description

Epi-Stop™ Nasal Gel is a sterile, single-use medical device supplied in a prefilled applicator for intranasal use by qualified healthcare professionals. The gel is intended to be applied locally within the anterior nasal cavity where it functions as a temporary physical barrier at the site of application. The device is provided ready for use in a single-use applicator and is intended for single patient use only.

Composition

Epi-Stop™ Nasal Gel contains porcine-derived gelatin (collagen source), hyaluronic acid, and a phosphate buffer solution. These components are combined into a sterile gel formulation designed for localized intranasal application by qualified healthcare professionals.

Intended Use

Epi-Stop™ Nasal Gel is intended for use by qualified healthcare professionals to provide a localized physical barrier within the anterior nasal cavity. The device may be applied directly to the site of bleeding or tissue disruption as part of standard clinical management at the discretion of the treating physician.

Contraindications

Epi-Stop™ Nasal Gel should not be used in patients with known hypersensitivity to gelatin, hyaluronic acid, or any device components. The device is not intended for use in cases of posterior epistaxis or bleeding originating from the posterior nasal cavity. The device should also not be used where surgical intervention or other definitive medical treatment is clinically indicated as determined by the treating physician.

Warnings and Precautions

Epi-Stop™ Nasal Gel is intended for single-patient use only and must not be reused or re-sterilized. Do not use the device if the sterile packaging is opened, damaged, or otherwise compromised. The device should be used using standard aseptic technique. The safety and effectiveness of repeated applications in the same patient have not been established. The device contains porcine-derived material and clinicians should consider this information when assessing patient suitability. The device is intended for use within the anterior nasal cavity only and should not be placed within the posterior nasal cavity. Care should be taken to avoid placement in a manner that could result in aspiration. If irrigation or removal of the gel is performed, sterile or previously boiled water should be used. The device is intended for topical intranasal application only and must not be injected intravascularly.

Instructions for Use

Prior to use, inspect the package to confirm that it is intact and that the product has not expired. Do not use the device if the packaging is damaged. Remove the applicator from the sterile package using aseptic technique. Position the patient according to standard clinical practice for the management of anterior nasal bleeding. Insert the applicator tip into the anterior nasal cavity without advancing beyond the nostril and apply the gel directly to the desired site within the anterior nasal cavity. Apply sufficient gel to cover the affected area and create a localized barrier. The amount applied and the duration of placement should be determined by the treating healthcare professional based on clinical judgment. After use, dispose of the applicator in accordance with institutional procedures for regulated medical waste.

Storage and Handling

Epi-Stop™ Nasal Gel is supplied sterile in a single-use applicator. The device should be stored according to the conditions indicated on the product label and should not be used after the expiration date printed on the package.

Possible Adverse Reactions

Potential adverse reactions associated with intranasal application may include local irritation, nasal discomfort, temporary nasal congestion, or hypersensitivity reactions. If an adverse reaction occurs, discontinue use and manage the patient according to standard clinical practice.

Adverse Event Reporting

Healthcare professionals are encouraged to report adverse events or product complaints to BioMed ENT, Inc. Reports should include the device lot number and a description of the event. Patient identifiers should not be included in reports.

Responsible Parties

BioMed ENT, Inc. is the legal manufacturer of Epi-Stop™ Nasal Gel and maintains responsibility for product design, manufacturing oversight, labeling compliance, and post-market surveillance in accordance with applicable FDA regulations.

BioMed ENT, Inc.
757 North Water Street, Suite 300
Milwaukee, Wisconsin 53202

Commercial distribution, order processing, and customer support for Epi-Stop™ Nasal Gel are provided by Grace Medical, Inc. Grace Medical, Inc. acts solely as the distributor of the product and does not perform product design, manufacturing, or post-market surveillance activities.

Grace Medical, Inc.
8500 Wolf Lake Drive, Suite 110
Memphis, Tennessee 38133

Symbol	Description
	CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use.
	Sterilized by steam.
	Single Use Only. Do no reuse.
	Do no re-sterilize.
	Do not use if package is damaged.

Symbol	Description
	Keep dry.
	Manufactured for
	Catalog number
	Lot number
	Expiration date (Use by). This device must not be used after the end of the year and month shown.

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