

Product information and instructions for use:

- 5 pre-filled sterile syringes with dressing gel.

Code HG0XX (with XX = syringe volume in ml);

- 5 sterile cannulas for the gel injection.

Code HGC00.

Description of the device.

HemoGel-ENT® is a post surgical dressing for nasal/sinus cavities based on carboxymethylcellulose (CMC), viscose thickener agents. The product comes as a matt white foaming gel, viscoelastic and dissolvable within few days through the normal sinus flow. The gel is applied in the nasal/sinus cavity after surgery or trauma to keep the mucosal surfaces separated during the healing process. During this phase, the padding effect of the gel can be used to control minor bleeding thanks to the action of its pressure. HemoGel-ENT® is dissolved through the normal sinus flow, alternatively the physician can choose to remove it by washing and suction.

Indications for Use

HemoGel-ENT® is used in patients undergoing surgery in nasal/sinus cavities as a filler gel to separate the mucosal surfaces, to prevent the adhesions and to help the normal healing process.

Contraindications

HemoGel-ENT® is contraindicated in patients with hypersensitivity to CMC.

Warnings and Precautions

- Before use, check the package to make sure it is intact and undamaged. Do not use the product if the package is opened or damaged.
- In rare cases, the particular physical and chemical conditions associated with nasal surgery procedures, both in the presence and absence of nasal packing, may present a risk of toxic shock syndrome (TSS). The warning signs of TSS include sudden fever, vomiting, diarrhea, dizziness, fainting (or near fainting upon standing) and / or skin rashes similar to sunburns.
- HemoGel-ENT® does not have antimicrobial properties, it is not bacteriostatic against pre-existing infection and does not prevent new infections.
- All assembly operations of the device must be carried out under aseptic conditions.
- We recommend using HemoGel-ENT® immediately after opening the package, discharging any unused parts of the product.
- As for most of adjuvant treatments of surgical procedures, there might be foreign body reactions.
- The product is dissolved in 4 days on average. A new application, if necessary, can be performed 4 days after the first application
- The remaining gel, not dissolved or expelled from the surgical site through the traditional ways, can be removed by gentle irrigation and suction.
- **Do not inject into the blood vessels.**
- The pre-filled cannula and syringe with gel are disposable; do not re-sterilize after use. Attempts to re-sterilize may result in cross-contamination.
- Do not use the product after the expiration date printed on the package.
- If any of the packages is damaged, do not use the product. Use a new one.

Instructions for use.

1. Open the package and place the syringe in a sterile field.
2. Remove the protective cap placed on the tip of the syringe and insert the cannula provided in the package.
3. Make sure the surgical site does not present excessive bleeding; it is advisable to control any excessive bleeding before applying HemoGel-ENT®.
4. Apply through the cannula a quantity of HemoGel-ENT® sufficient to cover the bone surface and mucous membranes.
5. Wait for 3-4 minutes and proceed with the awakening of the patient.
6. Give proper instructions to the patient to avoid sneezing or blowing of the nose in the first postoperative days.

Sterility

All parts of the product are supplied sterile and are for single use. Do not re-sterilize. Cover takes no responsibilities for the parts re-sterilized in healthcare facilities. Any attempts to re-sterilize may result in cross-contamination.














Storage conditions

Store in a cool, dry place away from heat and light. Store in the original package in a temperature range between + 5 ° C and + 30 ° C.

Manufacturer:

Cover Srl, Via Nizza 102, 10126 Torino (To) – Italy

www.cover-srl.com; info@cover-srl.com

Symbols used on the label			
	Do not reuse - Disposable		Manufacturer
	Product code		Sterilized by moist heat (Syringe)
	Sterilized by ethylene oxide (Cannula)		Read instructions for use
	Manufacturing lot		Keep away from heat and light sources.
	Date of expiration		Latex-free
	Temperature limits for storage		Do not use if the package is opened or damaged
	Medical Device in compliance with Directive 93/42/EEC and amendments		