

Eleviev™

Submucosal injectable composition 10 mL.
To facilitate endoscopic resection procedures.
10 mL per ampoule

PRESENTATION

Eleviev™ submucosal injectable composition is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

Eleviev™ is a sterile, colored clear emulsion to be used in endoscopic resection procedures during endoscopic examinations in the upper and the lower gastrointestinal tract, such as the esophagus, the stomach, the intestine and the rectum, designed to elevate the mucosal layer and the tissue to be excised from the submucosal and the external muscular layer.

Eleviev™ is sterilized by filtration and aseptically filled into a 10 mL polypropylene ampoule with a female Luer-lock closure that can easily be connected to a suitable disposable plastic or glass syringe with male Luer-lock connection fitting, to extract the emulsion, and be injected through an endoscope via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23 gauge (23G) or less (not provided with the device).

Eleviev™ is contained in 10 mL polypropylene ampoules pouched in an aluminum pouch under nitrogen, which is packed in a cardboard box.

COMPOSITION

The emulsion consists of the following components: Water for injection, Medium chain triglycerides, Poloxamer 188, Polyoxyl-15-Hydroxystearate, Sodium Chloride, Methylene blue.

DOSAGE AND ADMINISTRATION

Eleviev™ can be injected through an endoscope via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23 gauge (23G) or less (not provided with the device).

The administered dose of Eleviev™ should be determined based on the dimensions of the lesion to be removed.

Inject into the submucosa the amount of Eleviev™ needed to form a submucosal cushion of optimal height and shape for the lesion to be removed. During the procedure do not exceed a total dose of 50 mL per patient, either in single or in multiple administrations.

PROCEDURE

- Open the aluminum pouch and detach one ampoule from the strip.
- Open the ampoule by twisting off the cap following the arrow direction.
- Screw a disposable, sterile plastic or glass syringe with male Luer-lock connection fitting (not provided with the device) directly to the ampoule.
- Turn the ampoule upside down, extract the whole volume of the emulsion.
- Unscrew the disposable, sterile plastic or glass syringe from the ampoule, and expel the air from the syringe until some drops of the emulsion pour out of the tip.
- Securely screw the filled Luer-lock syringe to a suitable sterile endoscopic injection needle (not provided with the device).
- Fill the endoscopic injection needle with the emulsion and expel any air.
- Infuse a small quantity of the emulsion to determine the amount of force needed to inject the material.
- Retract the needle.

- Introduce the endoscopic injection needle through the working channel of the endoscope.
- Inject Eleviev™ immediately beneath the lesion to be excised in one, or in a series of injections around the base of the lesion.
- Discard the empty ampoule and store the unused ampoules inside the aluminum pouch into the folding box.

USES

Eleviev™ is a submucosal injectable composition to be used in endoscopic resection procedures in the upper and the lower gastrointestinal tract, such as the esophagus, the stomach, the intestine and the rectum. Eleviev™ is injected into the submucosa, beneath the lesion to be excised.

Eleviev™ is designed to provide a submucosal cushion of optimal height and duration, allowing the endoscopist an easy and safe resection procedure: endoscopic mucosal resection (EMR), hybrid EMR and endoscopic submucosal dissection (ESD).

Eleviev™ does not require any special apparatus or equipment, and it is designed to be used with the most common endoscopic resection devices.

The emulsion has physicochemical properties suitable for injection in the target site via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23 gauge (23G) or less (not provided with the device).

The ampoules are supplied with a female Luer-lock closure, to enable extraction of the emulsion with a common glass or plastic syringe with male Luer-lock connection fitting, to be subsequently connected to the endoscopic injection needle.

Following injection into the submucosa Eleviev™ reconfigures to occupy the interstitial space and forms a colored submucosal cushion of optimal height, that pushes the mucosa away from submucosal layer, allowing for an easy resection procedure.

Eleviev™, as a colored clear emulsion, helps to clarify the area where it is injected, to assist the endoscopist in visualizing the margins of the target lesion and performing the resection procedure, thereby decreasing the risk of damaging the external muscular layer, which could lead to perforation.

CONTRAINDICATIONS

Patients with known sensitivity to any of the components contained in Eleviev™.

WARNINGS AND PRECAUTIONS

- The endoscopist injecting Eleviev™ must be experienced in the administration technique.
- The safety of Eleviev™ has not been established in pregnant or lactating women or in children under 18 years of age.
- Eleviev™ is provided in single use ampoules. Eleviev™ should not be reused after first opening. Any emulsion not injected during the procedure should be not reused for another endoscopic procedure.
- Do not use if the primary packaging (ampoule) or secondary packaging (aluminum pouch) is damaged.
- Do not use if the twist-off cap is damaged.
- Do not use if the emulsion is not clear, shows any signs of opalescence or contains floating or precipitated visible particles.
- The product compatibility with other substances has not been tested.

ADVERSE REACTIONS

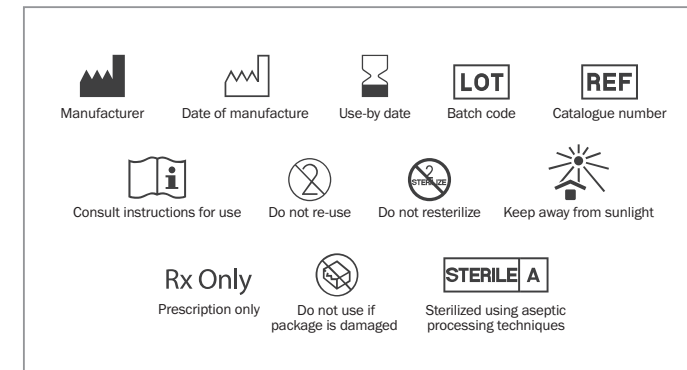
Rarely, local bleeding and/or inflammatory reaction could occur which

may or may not be associated with Eleviev™.

STORAGE

Store between 2°C (35.6°F) and 25°C (77°F).
Excursions permitted up to 40°C (104°F).
Protect from light. Do not freeze.
Do not use if packaging is damaged.
Sterile product for single use only.
Do not use after expiration date.
Revision n°: 07, Date: May 2017.

DESCRIPTION OF USED SYMBOLS



US Patent Nos. 9,226,996, 9,364,580 and 9,522,216



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