



Frequently Asked Questions Eleview™

1. What is Eleview?

Eleview is an injectable liquid composition that is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to removal with a snare or endoscopic device. It facilitates 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.

2. Describe Eleview

Eleview is a colored (blue), sterile, clear emulsion used as a submucosal injection composition that helps clarify the area where it is injected. It assists the endoscopist in visualizing the margins of the target lesion and performing the resection procedure, thereby helping to decrease the risk of damaging the external muscular layer and potential perforation.

3. How does Eleview work?

Eleview is designed to elevate the mucosal layer and the tissue to be excised from the submucosal and the muscular layer, thereby allowing the endoscopic an easy and safe mucosal resection (EMR), hybrid EMR and endoscopic submucosal dissection (ESD).

4. How long does Eleview work?

Eleview is designed, upon injection, to reconfigure and occupy the interstitial space, creating a submucosal cushion of optimal height and duration that allows for an easier resection procedure. As demonstrated in extensive animal studies (data on file), Eleview separates the mucosal layers up to 45 minutes. Please contact Aries Medical Affairs for additional information.

5. What is contained within Eleview?

The emulsion consists of the following: water for injection, medium chain triglycerides (the oily phase), poloxamer 188 (the bulking/cushioning agent), polyoxyl-15-hydroxystearate (the surfactant), sodium chloride (osmotic agent), and methylene blue (a dye).

6. Why does Eleview contain Methylene Blue?

Eleview is dyed with methylene blue because it helps in visualizing the lesion and performing the resection procedure, thereby helping to minimize the risk of perforation. In addition, the staining of submucosal layer will help facilitate the identification of muscle injury.

7. How is Eleview supplied?

Eleview comes in 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 a male Luer-Lock connection fitting so that Eleview can be extracted and then 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).

8. What is the procedure for the preparation of Eleview™ for injection?

Preparation of Eleview for injection is as follows:

1. Open the aluminum pouch, detach one ampoule from the strip, and then open the ampoule by twisting off the cap following the arrow direction.
2. Screw a disposable, sterile plastic or glass syringe with male Luer-lock connection fitting (not provided with the device) directly to the ampoule.
3. Turn the ampoule upside down, extract the whole volume of the emulsion.
4. 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.
5. Securely screw the filled Luer-lock syringe to a suitable sterile endoscopic injection needle (not provided with the device).
6. Fill the endoscopic injection needle with the emulsion and expel any air.
7. Infuse a small quantity of the emulsion to determine the amount of force needed to inject the material.
8. Retract the needle.
9. Introduce the endoscopic injection needle through the working channel of the endoscope.
10. Inject Eleview immediately beneath the lesion to be excised in one, or in a series of injections around the base of the lesion.
11. Discard the empty ampoule and store the unused ampoules inside the aluminum pouch into the folding box.

9. Where is Eleview injected?

Eleview is injected into the submucosa beneath the lesion to be excised in one or in a series of injections around the base of the lesion.

10. How much Eleview do you inject?

The dose to be administered is determined based on the dimensions of the lesion to be removed. Inject enough Eleview to form a submucosal cushion of optimal height and shape for the lesion to be removed. Do not exceed 50 mL per patient, either in single or multiple injections, during one endoscopic procedure.

11. Can I reuse an opened ampoule of Eleview on another patient?

No. Eleview is provided in ampoules that are intended for a single use only. Any emulsion in an opened ampoule that was not injected should not be used for another patient.

12. What size needle can Eleview pass through?

Normal, commercially available endoscopic injection needles can be used. For example, a 2.3 mm x 230 cm endoscopic injection needle having a needle diameter of 23 gauge or less (not provided with Eleview) can be used.

13. Does Eleview require any special apparatus or equipment?

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

14. What adverse events have been observed with Eleview™?

Rarely, local bleeding and/or inflammatory reaction could occur which may or may not be associated with Eleview.

15. Are there any contraindications to using Eleview?

Patients with any known sensitivity or allergy to any of the components contained in Eleview should not receive the product.

16. Are there any warnings and precautions I should know about?

- The endoscopist injecting Eleview must be experienced in the administration technique.
- The safety of Eleview has not been established in pregnant or lactating women or in children under 18 years of age.
- Eleview is provided in single use ampoules. Eleview™ 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.

17. Does Eleview interact with other drugs?

The interaction of Eleview with other drugs has not been tested.

18. How can I report a device-related adverse event or product complaint related to Eleview?

Please call our toll-free customer service number at 888-274-3708, option #1.

19. Are there any studies looking at the efficacy of Eleview?

There is currently an ongoing human trial to evaluate the comparative efficacy and safety of Eleview in subjects undergoing endoscopic mucosal resection. The study should be completed by mid-2017. Extensive pre-clinical animal testing was conducted in support of the FDA submission and 510(k) clearance of Eleview.

20. How can I order Eleview?

Eleview can be ordered from **Aries Pharma-Specialty Pharma Services:**

Email: gmb-sps-aries@cordlogistics.com

Fax: 614-553-6137

Customer must provide: purchase order number, item requested, and quantity requested. An Eleview Order Form is available through your Aries Sales Specialist or through Customer Service. For questions, Customer Service may be reached at **888-ARIES-08** (888-274-3708).

21. If I order Eleview, how many ampoules will I receive in one order?

In one box, there are 5 individual ampoules each containing 10 mL of Eleview.

22. How do I store Eleview™?

Eleview should be protected from light and stored between 35.6°F (2°C) and 77°F (25°C).

23. Who developed Eleview?

Eleview was developed by Cosmo Pharmaceuticals, N.V. which is a specialty pharmaceutical company that aims to become a global leader in the market of optimized therapies for selected gastrointestinal diseases.

24. How can I obtain additional medical information on Eleview?

Please call our toll-free customer service number at 888-274-3708, option #2 for medical information. Also, please visit EleviewUS.com for additional information.

25. How is Eleview shipped?

To protect the 10ml ampoules from freezing or excessively high temperature, Eleview is shipped in a thermo-protective container with ambient gel packs and includes an irreversible descending temperature indicator.

26. How is Eleview packaged?

Eleview is sold as a five ampoule pack box, with each ampoule containing 10ml of product in a protective foil pouch. Eleview second level packaging has five sales units (with 5 ampoules each), in a secondary carton. Eleview case level packaging has four secondary packing cartons, containing 20 sales units in each case.

27. What is the expiration date for Eleview?

See the outer carton, foil pouch or individual ampoule for expiration date. Currently, the expiration date is two years after the date of manufacture.

28. Who manufactures Eleview?

Eleview is manufactured and packaged for Cosmo Technologies, LTD in Ireland and imported and distributed by Aries Pharmaceuticals, Inc. in the US

29. Is Eleview distributed outside of the US?

Currently, Eleview is only distributed in the US by Aries Pharmaceuticals, Inc. a wholly owned subsidiary of Cosmo Technologies Ltd.

30. What is the barcode/GTIN (UDI) Number for Eleview?

Following are the GTIN (UDI) numbers for Eleview:

Package Level	Description	GTIN (UDI)
Base Unit	Individual 10ml ampoule	5391530190008
Inner Pack	Folding Box containing 1 foil pouch of 5 ampoules	5391530190015
Case	Inner box containing 5 folding boxes	5391530190022
Case	Outer box (contains 4 inner boxes) = 20 folding boxes	5391530190039

31. I received an Eleview™ shipment and the temperature indicator in my box is green. What does this mean?

If the center dot is green, then the product is usable. Please continue to store the product between 35.6°F (2°C) and 77°F (25°C).



32. I received an Eleview shipment and the temperature indicator in my box is red. What does this mean?

If the center dot is red, then the product has been exposed to a temperature that rendered the product not usable. We will be glad to send you replacement product. May I have your contact information so we can send you a new shipment (send to Cardinal SPS for account lockup and fulfillment).



33. Why is Eleview classified by FDA as a medical device and not as a drug?

In gastrointestinal endoscopic procedures, the primary intended purpose of Eleview is for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device. Eleview is an injectable composition which, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure (EMR, ESD or polypectomy). This primary intended purpose is achieved mechanically, not through chemical action within or on the human body, and is not dependent on being metabolized.

FDA regulates medical products as drugs or devices, when they are intended to cure, treat, mitigate, diagnose, or prevent disease in humans, or affect the structure or function of the human body.

A regulated medical product is classified as a drug if it achieves its primary intended purposes through chemical action within or on the human body. If the medical product does not achieve its primary intended purposes through chemical action on or within the body, and is not dependent upon being metabolized for the achievement of its primary intended purposes, it is classified as a medical device.

The primary intended purpose of Eleview is submucosal lift, which is a mechanical action. Eleview does not achieve this primary intended purpose through chemical action within or on the body, and is not dependent on being metabolized for the achievement of its primary intended purposes. Therefore,

FDA classifies Eleview as a medical device under a regulation published at 21CFR876.1500, "Endoscope and accessories," where accessories are identified as devices which may assist in gaining access or increase the versatility and augment the capabilities of the devices. More explanation, including the FDA statutory definitions of drug and device, may be found in the FDA draft guidance document, Classification of Products as Drugs and Devices (June 2011), available at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm>.

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