Individually Pouched Allevio™ Applicator
INSTRUCTIONS FOR USE

The Allevio™ Applicator is a latex-free, sterile, prescription device for single use by medical professionals only.

INTENDED USE
The Allevio™ Applicator is designed to administer small amounts of medicine or fluid into the nasal cavity, including the area of the pterygopalatine fossa and sphenopalatine ganglion for the purpose of treating disorders.

CONTRAINDICATIONS
Do not use the Allevio™ Applicator if one or more of the following conditions exist:

• acutely inflamed nasal membranes,
• active swelling or bleeding from the nose,
• malignancy, granulomatous disease, or other condition disrupting the nasal mucosa, and
• mechanical blockage to nasal passage.

PRODUCT DESCRIPTION
The Allevio™ Applicator is made of a soft urethane material, it is latex-free, and is a single use disposable nasal applicator intended for use in the nasal cavity and with solutions that are appropriate for nasal administration. It consists of an inner catheter with a preformed curved distal tip that is actuated from within a more rigid outer sheath. A standard luer lock connects a syringe to the catheter. The medical professional controls the medicine or fluid chosen, the volume of medicine or fluid delivered. The tip of the Allevio™ Applicator is made of a soft urethane material for minimum discomfort or damage to the nasal mucosa.

COMPLICATIONS
The Allevio™ Applicator should be used only by medical professionals. Complications may include:

• Irritation to nasal cavity or mucosa, nose bleeding, brief medicine taste in the back of the throat; and/or mild pain.

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WARNINGS AND PRECAUTIONS

Warnings
1. If nasal mucosa appears irritated or swollen, or if patient experiences significant pain, immediately discontinue using the Allevio™ Applicator.
2. Avoid excessive or unnecessary contact with nasal mucosa.
3. Do not force the tip of the Allevio™ Applicator into the nose.
4. Remove the device immediately if bleeding occurs, implement standard epistaxis protocols and reschedule the procedure.
5. Exercise caution if patient has any type of bleeding disorder such as Von Willebrand’s disease or hemophilia or has a history of frequent or unexplained nose bleeds.

Precautions
1. The Allevio™ Applicator is only available by prescription.
2. The Allevio™ Applicator is a sterile disposable device for single patient use only.
3. Discard appropriately after single patient use.

USE AND STORAGE
Store at ambient temperature and humidity.

INSTRUCTIONS FOR USE
The Allevio™ Applicator is designed to administer small amounts of medicine/fluid into the nasal cavity, including the area of the pterygopalatine fossa and sphenopalatine ganglion for the purpose of treating nasal disorders. The following procedure is recommended to instill medicines or fluids into the nasal cavity.

1. Visually inspect package containing the Allevio™ Applicator for damage. If sterility is broken and/or any damage is visible do not use the Allevio™ Applicator. Slide the inner catheter into and out of position to ensure that the device is easily actuated.

Caution: Allevio™ Applicator is shipped with the inner catheter in the extended position to preserve the preformed curve at the distal tip of the catheter as shown in Fig. 1 (above) and Fig. 2 (below). If this angle is not present as pictured, do not use the Allevio™ Applicator.

2. Temperature strips are included in the event that you want to monitor the temperature of your patients. Two adhesive temperature strip are available in the package for use on each cheek.

3. Pre-medicating the nasal passage with a suitable topical anesthetic may limit discomfort or irritation.

4. Fill syringe with the desired quantity of medicine or fluid.

5. Retract inner catheter into outer sheath as shown below.

Figure 1. Allevio™ with extended and shaped tip as shipped.

Figure 2. Allevio™ shown in the extended and curved tip as shipped.

PATENT PENDING
6. With the hub directional indicator facing anteriorly, advance **Allevio™** Applicator into the anterior nasal passage, staying anterior to the middle turbinate or middle nasal concha, until catheter tip gently contacts the superior mucosa overlying the cribiform plate (see Fig. 4). Avoid excessive contact or force with the nasal mucosa while advancing the **Allevio™** Applicator. Most accurate placement results are achieved by keeping the **Allevio™** close to the anterior nasal mucosa until the applicator is past the middle turbinate or middle nasal concha.

**Caution:** If excessive resistance is encountered or if patient experiences significant discomfort, do not force **Allevio™** Applicator into the nasal passage.

7. Withdraw **Allevio™** approximately 3-5 millimeters and stabilize position.

8. With the hub directional indicator facing anteriorly, actuate the inner catheter into the extended position. The catheter should slide easily; if significant resistance is encountered or patient experiences significant discomfort, withdraw the **Allevio™** Applicator a few millimeters, allowing the inner catheter to fully advance without further contacting the superior nasal mucosa (see Fig. 5).

9. Connect **Allevio™** to a syringe filled with the desired quantity of medicine or fluid via the standard Luer-Lock fitting.

10. Ensure proper positioning with fluoroscopic guidance then dispense medicine or fluid. (Fluoroscopic guidance is not necessary but can provide an additional aid in placement location)

11. To ensure maximum coverage the catheter can be rotated slightly several degrees while instilling medication to achieve a more even distribution.

12. Remove the **Allevio™** Applicator and repeat the procedure through the other nostril as necessary.

**CONTACT INFORMATION**

**Warning:** If you observe a defect or experience a problem with this device please contact:

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