VECTRA™ F Drug Delivery Microsponge for the Frontal Ostia

Instructions for Use

Contraindications:

Vectra should not be used on patients who have known allergies to shellfish.

Intended Use:

The Vectra F Drug Delivery Microsponge for the Frontal Ostia is intended specifically to administer medicinal substances to treat nasal disorders. Vectra has been evaluated for suitability only with the following corticosteroid medicines:

- Triamcinolone acetonide suspensions

Vectra is intended for use under the direction of a licensed healthcare provider.

Description:

Vectra is constructed of a patient-comfortable microsponge which is manufactured from naturally occurring chitosan polymers. Vectra was specifically engineered for use as a drug delivery device to provide sustained delivery of medicines to treat nasal disorders. Vectra is supplied as a compressed device which rapidly wicks the medicine and immediately expands to fill the space desired for treatment and an applicator tool to facilitate placement and hydration of the device. Vectra can absorb up to 0.4 cc of medicine and expands up to 7 mm OD x 15 mm long. The exact amount of medicine loading and expansion will depend upon the patient anatomy and the space available for expansion. After treatment with the medicine, Vectra will be naturally eliminated via mucociliary action, assisted by daily irrigation with fluid as prescribed by a licensed healthcare provider.

Warnings and Precautions:

- Vectra is not bacteriostatic toward pre-existing infections, nor does it prevent the occurrence of new infections. Appropriate treatment to be instituted in case of infection.
- Single Use Only.
- Sterility is not guaranteed if the package is damaged or opened. Discard damaged or opened packages.
- To prevent product contamination prior to application, always follow aseptic techniques.
- Clinician must inform the patient that the device contains materials derived from shellfish.
- In rare instances, the physiochemical condition associated with nasal surgery, both with and without nasal packing, may present a risk of toxic shock syndrome (TSS).
- Appropriate treatment to be instituted in case of infection.
- In the case of prolonged bleeding seek medical attention.
- Do not ingest.
- Do not inhale.
- Do not use after the end of the year and month shown.
- Vectra should be kept dry prior to use.
- This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.
- Vectra is intended for topical use only.
- Vectra has not been tested for use with other devices or medicines other than those defined in the intended use. Use only according to labeled instructions.

Instructions for Use:

1. Using sterile techniques to maintain product integrity, peel open the 4.5” x 13.5” pouch and remove the applicator tool and Vectra foam microsponge. Grasp the shaft of the tool between the thumb and the forefinger in the pickout area near the tip of the tool and remove the tool from the support tray. Place the tool in the sterile field. Note the Vectra foam is further packaged inside of a soluble sheath that will dissolve and clear upon application.
2. Screw a syringe filled with approximately 2 ml of medicine onto the luer hub at the base of the tool.
3. Insert Vectra longitudinally into the frontal ostium via the tool until only approximately 1 mm of foam is visible and hydrate it with the syringe over the course of 15 – 20 seconds. Remove the tool and syringe from the patients nose and discard.
4. If Vectra is broken during insertion, assess if the size is appropriate for application. If not, dispose and reapply a new Vectra.
5. Discard any unused product after opening.
6. Begin daily irrigation of the placed Vectra after 3 days.
7. Vectra will be naturally eliminated between 3 to 6 days following daily hydration.

How Supplied:

Vectra is terminally sterilized by gamma irradiation.
See pouch and carton labels for package quantity.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Store at room temperature.

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Made in USA. Patented.

Symbol	Description
℞ ONLY	CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician
#	Quantity Symbol: numeral in symbol (in place of #) indicates the quantity of units in package.
	Caution: See Instructions for Use
STERILE R	Sterilized by Irradiation
2	Single Use Only. Do not reuse.
2 STERILIZE	Do Not Re-sterilize
	Do Not Use if Package is Damaged
	Keep Dry
	Manufacturer
REF	Catalog Number
LOT	Lot Number
	Expiration Date (Use By). This device should not be used after the end of the year and month shown.

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