



## Drug Delivery Microsponge for the Frontal Ostia

### Instructions for Use

#### Contraindications:

**Vectra F15 should not be used on patients who have known allergies to shellfish.**

#### Intended Use:

The Vectra F15 Drug Delivery Microsponge for the Frontal Ostia is intended specifically to administer medicinal substances to treat nasal disorders. Vectra F15 has been evaluated for suitability only with the following corticosteroid medicines:

- Triamcinolone acetonide suspensions

Vectra F15 is intended for use under the direction of a licensed healthcare provider.

#### Description:

Vectra F15 is constructed of a patient-comfortable microsponge which is manufactured from naturally occurring chitosan polymers. Vectra F15 was specifically engineered for use as a drug delivery device to provide sustained delivery of medicines to treat nasal disorders. Vectra F15 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 F15 can absorb up to 4 cc of medicine and expands up to 15 mm OD x 20 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 F15 will be naturally eliminated via mucociliary action, assisted by daily irrigation with fluid as prescribed by a licensed healthcare provider.

#### Warnings and Precautions:

- Vectra F15 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 F15 should be kept dry prior to use.
- This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.
- Vectra F15 is intended for topical use only.
- Vectra F15 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.

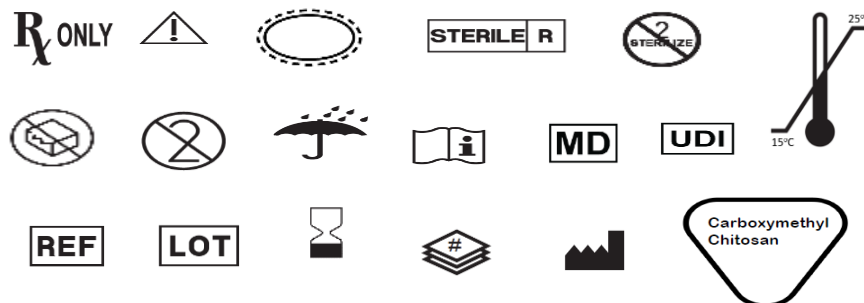
#### Instructions for Use:

1. Using sterile techniques to maintain product integrity, peel open the 4.5" x 13.5" pouch and remove the applicator tool and Vectra F15 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 F15 foam is further packaged inside of a soluble sheath that will dissolve and clear upon application.
2. Screw a syringe filled with approximately 5 ml of medicine onto the luer hub at the base of the tool.
3. Insert Vectra F15 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 patient's nose and discard.
4. If Vectra F15 is broken during insertion, assess if the size is appropriate for application. If not, dispose and reapply a new Vectra F15.
5. Discard any unused product after opening.
6. Begin daily irrigation of the placed Vectra F15 after 3 days.
7. Vectra F15 will be naturally eliminated between 3 to 6 days following daily hydration.



















#### How Supplied:

Vectra F15 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.**



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	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
	Quantity Symbol: numeral (in place of #) indicates the quantity of units in package.
	Caution: See instructions for Use.
	Single sterile barrier system with protective packaging outside
	Sterilized by irradiation.
	Single Use Only. Do not reuse.
	Do Not Resterilize.
	Do Not Use if Package is Damaged.
	Contains material derived from Shellfish
	Keep Dry.
	Store at room temperature between 15°C and 25°C.
	Medical Device
	Manufacturer
	Catalog Number
	Lot Number
	Expiration Date (Use By): This device should not be used after the expiration date.
	Unique Device Identifier
	Consult Instructions for Use

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