



# VELNEZ®

## The Optimal Healing Solution



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### CATEGORY

Nasal Pack

### TRADE NAME

VelNez®

### DESCRIPTION

VelNez® is a fragmentable composite that fragment within a few days on application intended as a nasal dressing. The pain associated with the traditional nasal pack removal is completely eliminated with VelNez® since such a procedure is not necessary as VelNez® fragments uniformly. It will also promote healing and reduce the clotting time.

### INTENDED USE

The fragmentable VelNez® is intended to be used in the nasal/sinus cavity in Rhinoplasty, Septoplasty, Rhinosseptoplasty, Functional Endoscopic Sinus Surgery (FESS), Sinoplasty, Turbinate reduction, surgery or trauma patients. It acts as a space occupying dressing, preventing adhesion by separating the compromised mucosal surfaces. It also helps in healing and achieving haemostasis.

### INSTRUCTIONS FOR USE OF VELNEZ® NASAL DRESSING

**Step 1: Removal from Package** – Open the blister pack by removing the paper film and take out VelNez®.

**Step 2: Pre-insertion** – If required cut the VelNez® using sterile apparatus.

**Step 3: Insertion** – Using sterile nasal dressing forceps place VelNez® inside the nasal cavity at the site of application and irrigate using saline solution if required.

**Step 4: Confirm** - Confirm that VelNez® is placed at the intended position. VelNez® will fill itself by absorbing the surrounding fluids and blood.

*\*Note:* We recommend to irrigate the dressing in regular interval with saline for desired fragmentation.

### CONSTITUENTS

Gelatin (BSE/TSE agent free) Chitosan, Polyvinyl Alcohol, Psyllium Husk

### WARNING & PRECAUTIONS

- Do not re-sterilize.
- Do not re-use.
- Use the device prior to the “Use by (M)” specified on the package.
- To be used by Registered Medical Practitioner or a hospital
- Do not use if package is damaged.
- Discontinue use if application area shows signs of infection, irritation, maceration (whitening of surrounding skin) or itching & consult a healthcare professional.
- Should not be used for patients with coagulation disorders.

### RISK OF REUSE

VelNez® is supplied sterile for single use only. Do not re-sterilize as this may change product characteristics and lead to failure of intended use of the product.

Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and /or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease from one patient to another and loss of uptake of device and reduced the efficacy is prominent. No other consequences will happen.

Damaged, unused, opened packages of VelNez® should be discarded as per disposal instructions, sterility of the product is not guaranteed when the packaging is damaged or unused portion of the device is left in the pack.

### INDICATIONS

As nasal pack for hemorrhage control or/and prevention of adhesion after nasal surgery, Septoplasty with and without Functional endoscopic sinus surgery (FESS) and turbinoplasty.

### HOW SUPPLIED

VelNez® is supplied as a sterile, single-use Nasal Pack.

### CONTRAINDICATION

No known contraindications and adverse reactions reported.

Note: Do not use VelNez® if you are allergic (Hypersensitive) to its constituents.

### NOTICE TO THE USER/ PATIENT

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

### DISPOSAL OF DEVICE

Discard as per the hospital biomedical waste management system prevailing in the premises meeting local or national regulatory laws.

### PATIENT POPULATION

Patients with age group from 18-60 years of age.

### INTENDED USER

Surgeon, ENT specialist

### STORAGE

VelNez® should be stored at a temperature between 4°C to 30°C. Keep away from direct sunlight. Store in Dry place.


















### SHELF LIFE

3 Years from the date of Mfg.

### STERILIZATION METHOD

Gamma Irradiation

## DEFINITION OF SYMBOLS USED

Symbol	Description
	Lot / Batch Number
	Manufacturing Date
	Use by
	Manufacturer
	Do not Reuse
	Do not Re-sterilize
	Sterilized using Irradiation (Gamma Radiation)
	Do not use if package is damaged
	Keep away from sunlight
	Store in dry place
	Storage Temperature
	Caution
	Instructions for use
	Latex Free
	Catalogue Number
	Animal origin
	Medical Device