VELNEZ®

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NAME & ADDRESS OF THE MANUFACTURER:

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CATEGORY
Ear Pack

TRADE NAME
VelNez®

DESCRIPTION
VelNez® is a biodegradable composite that degrades within a few days on application and is intended as an ear dressing. VelNez® degrades within 20 days of application. It will also reduce fibrosis and at the same time promote healing and reduce the clotting time. During ear procedures, it can be applied to control compression of tissue, middle ear structure and prevent adhesion.

INTENDED USE
VelNez® is intended to be used as a packing dressing in the middle and external ear cavity after surgery. It acts as a space occupying dressing, preventing adhesion by separating the compromised mucosal surfaces. It also helps in wound healing and achieving haemostasis.

INSTRUCTIONS FOR USE OF VELNEZ® NASAL/ EAR DRESSING
Step 1: Removal from Package – Open the pack by removing the paperfilm and take out VelNez®.
Step 2: Pre-insertion – If required cut the VelNez® using sterile apparatus.
Step 3: Insertion – Using sterile apparatus, place the VelNez® inside ear cavity at the site of application.
Step 4: Confirm - Confirm that the device is placed at the intended position. VelNez® will fill itself by absorbing the surrounding fluids and blood.

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 (⏳)" specified on the package.
- To be used by Registered Medical Practitioner or a hospital
- Do not use if package is damaged.
- Discontinue the use if the application area shows signs of infection, irritation, maceration (whitening of surrounding skin) or itching & consult a healthcare professional.
- Should not be used for the 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. 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 ear pack for hemorrhage control or/and prevention of adhesion between the compromised surfaces after an ear surgery, traumatic bleeding. Tympanoplasty, Tympanostomy or Myringoplasty and other outer and middle ear surgeries.

HOW SUPPLIED
VelNez® is supplied as a sterile, single-use product in one 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 meeting local or national regulatory laws.

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

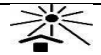
INTENDED USER
Surgeon, ENT specialist

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