

SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement

Product Codes: 8195060, 8195080

Consumer Medical Device Information

What is in this leaflet

This leaflet answers some common questions about SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement. It does not contain all the available information. It does not take the place of talking to your surgeon.

All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement against the benefits that are expected. This leaflet does not contain all the available information about SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement. Your surgeon has been provided additional information and can answer any questions you may have. Follow your surgeon's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it in future if needed.

What is SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement?

SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement is used for fixation of prostheses to living bone in joint arthroplasty procedures where infection by gentamicin sensitive organisms is a potential risk

The bone cement is indicated for use in children only in the case of limb preservation where no other procedure is likely to give a good chance of successful treatment.

The bone cement should be used with an appropriate prosthesis.

SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement consists of SmartMix Cemvac, a vacuum mixing syringe system pre-filled with bone cement powder and liquid. The device is for single use only and reduces exposure to monomer

fumes during the preparation of bone cement.

. Bone cements have no adhesive properties, but instead rely on close mechanical interlock between the irregular bone surface and prosthesis.

SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement can only be implanted surgically by a qualified surgeon, who will choose the appropriate treatment for you. As with any medical treatment, individual results may vary.

When should SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement not be used?

SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement should not be used in patients with:

- the presence of the condition Myasthenia Gravis
- hypersensitivity to gentamicin, or to any other of the cement components
- other potentially ototoxic or nephrotoxic drugs.

If you are unsure whether SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement should be used in your treatment, talk to your surgeon.

What to do after SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement has been implanted?

Joint replacement is a significant operation. While most people have a good result and an active recovery, there are potential surgical/medical risks and recovery takes time. Ask your surgeon for more details and talk to them if you have any unusual symptoms such as:

- Infection
- Worsening of original symptoms
- Loosening or displacement of the prosthesis.

After surgery, it is important to follow the instructions of your surgeon to aid in healing, reduce recovery time, and increase mobility and strength. This may include restricting movement during the initial healing phase followed by specific rehabilitation exercises.

Magnetic Resonance Imaging (MRI) Safety Information

Having SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement implanted does not prevent you from having MRI scans. Please consult with your physician.

Reporting adverse effects

If you wish to report any adverse effects you believe are a result of SmartMix Cemvac pre-filled with SmartSet GHV Gentamicin Bone Cement please talk with your surgeon or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com.

Reports may also be made directly to the Therapeutic Goods Administration via the website:

<https://www.tga.gov.au>

Sponsor

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