

Product description - ORCEM 1G & ORCEM 3G

ORCEM 1G & ORCEM 3G is a radiopaque acrylic bone cement manufactured in compliance with ISO 5833 standards (Implants for surgery -- Acrylic resin cements). Its self curing specifications allow an immediate and stable fixation of surgical implants into the bone during orthopaedic surgery. It contains an antibiotic issued from family of aminosides: the gentamicin.

ORCEM 1G & ORCEM 3G is made of two sterile components: the polymer (powder) and the liquid monomer. These two components are in a double sterile packaging. Each unit contains a sterile ampoule of liquid within a blister pack and a powder within a sterile double pouch, and in a third packaging aluminium pouch to protect from humidity. Both components are packaged in a box. The liquid component is mainly composed of methyl methacrylate. The major powder component is polymethylmethacrylate (PMMA). Benzoyl peroxide which initiates the polymerization is included in the polymer powder.

Indications

ORCEM 1G & ORCEM 3G bone cement with gentamicin is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

Composition

| | ORCEM 1G & ORCEM 3G (% w/w) |
|--|--------------------------------|
| LIQUID | |
| Methyl methacrylate | 84.4 |
| Butyl methacrylate | 13.2 |
| N, N dimethyl-p-toluidine | 2.4 |
| Hydroquinone | 20 ppm |
| POWDER | |
| Polymethylmethacrylate | 84.3 |
| Benzoyl peroxide | 2.3 |
| BaSO ₄ | 9.6 |
| Gentamicin sulfate corresponding to 1g | 3.8 |

| | ORCEM 1G Ref: F9001011 | ORCEM 3G Ref: F9001013 |
|---------------|---------------------------|---------------------------|
| LIQUID | 14.4g | 16.4g |
| POWDER | 41.6g | 41.6g |

LIQUID COMPONENT

The liquid component is mainly composed of methyl methacrylate. Butyl methacrylate acts as a co-monomer. Hydroquinone is present in very small quantities as a stabiliser to prevent premature polymerisation which may occur when the liquid is subjected to excessive heat or light. N, N dimethyl - p -toluidine is present as an activator to promote polymerisation when the powder and liquid are mixed.

POWDER COMPONENT

The major component is polymethylmethacrylate (PMMA). The benzoyl peroxide which initiates the polymerisation is included in the polymer powder.

In order to get the required setting times and viscosities, various marketed PMMA powder having different granulometries and molecular weights are mixed in adequate proportions. Barium sulphate, the radiopaque agent, is included up to 4 grams by unit and complies with the European pharmacopoeia.

Gentamicin ensures prevention of infection following operation.

Reference

| Designation | Reference number |
|---------------------|-------------------------|
| ORCEM 1G (40 grams) | F9001011 |
| ORCEM 3G (40 grams) | F9001013 |

ORCEM 1G

Qty. 1

MATERIAL :
Powder (41,6 g) : Polymethylmethacrylate, Benzoyl peroxide, Barium sulphate, Gentamicin sulphate corresponding to 1 g base
Liquid (14,4 g) : Methyl methacrylate, Butyl methacrylate, N-N dimethyl-p-toluidine, Hydroquinone

(EN) Surgical Cement with Gentamicin-High Viscosity. (FR) Ciment chirurgical avec gentamicine-Haute viscosité. (DE) Chirurgischer Zement mit Gentamicin-hohe Viskosität. (BG) Хирургически цимент с гентамицин-Висок вискозитет. (EL) Χειρουργικό τσιμέντο με γενταμικίνη-Υψηλό ιξώδες. (HR) Kirurški cement s gentamicinom-Visoka viskoznost. (DA) Kirurgisk cement med gentamicin-Høj viskositet. (ES) Cemento quirúrgico con gentamicina-Alta viscosidad. (ET) Kirurgiline tsement gentamüsiiniga-Kõrge viskoossus. (FI) Kirurginen sementti, sisältää gentamisiinia-Korkea viskositeetti. (SV) Kirurgiskt viskosidad. (ET) Kirurgiline tsement gentamüsiiniga-Kõrge viskoossus. (FI) Kirurginen sementti, sisältää gentamisiinia-Korkea viskositeetti. (SV) Kirurgiskt cement med gentamicin-Hög viskositet. (HU) Sebészeti cement gentamicinnel-Magas viskozitás. (IT) Cemento chirurgico con gentamicina-Alta viscosità. (LV) Ķirurģiskais cements ar gentamicīnu-Augsta viskozitāte. (LT) Chirurginis cementas su gentamicinu-Didelis klampumas. (PL) Cement chirurgiczny z gentamycyną-Duża lepkość. (PT) Cimento cirúrgico com gentamicina-Alta viscosidade. (CS) Chirurgicalký cement s gentamicinem-Vysoká viskozita. (RO) Ciment chirurgical cu gentamicină-Vâscozitate mare. (SK) Chirurgický cement s gentamicinom-Vysoká viskozita. (SL) Kirurški cement z gentamicinom-Visoka viskoznost. (NO) Kirurgisk sement med gentamicin-Høy viskositet. (TR) Gentamisinli cerrahi çimento-Yüksek viskozite

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ISO 5833



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