

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