

Product Description – BEZCEM 1&3

BEZCEM 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.

BEZCEM 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 double peelable pouch, the whole being 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

BEZCEM® 1&3 bone cement is indicated for fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

Composition

	BEZCEM 1 (% w/w)	BEZCEM 3 (% w/w)
Liquid phase	14.4g	16.4g
Methylmethacrylate	84.4	84.4
N-Butyl methacrylate	13.2	13.2
N,N Dimethyl-p- toluidine	2.4	2.4
Hydroquinone	20 ppm	20 ppm
Powder phase	40g	40g
Polymethylmethacrylate	87.6	87.6
Benzoyl Peroxide	2.4	2.4
Barium sulphate	10.0	10.0

This type of cement is made of two sterile components: the polymer in 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 double peelable pouch, the whole being packaged in a box.

The monomer liquid is sterilised by microfiltration. The blister pack containing the ampoule is sterilised by ethylene oxide. Sterilisation of the powder component within its double peelable pouch is achieved by gamma radiation.

Quantity in each package:

	BEZCEM 1 (40 grams) Ref : 410001	BEZCEM 3 (40 grams) Ref : 410003
LIQUID	14.4g	16.4g
POWDER	40g	40g

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.

References

Designation	Volume	Reference number
BEZCEM 1 (Standard viscosity)	40 grams	410001
BEZCEM 3 (Low viscosity)	40 grams	410003