

UNITE® AB BONE CEMENT

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Overview

UNITE® AB Bone Cement is a high-viscosity, radiopaque bone cement containing and releasing gentamicin sulphate for manual application. UNITE® AB Bone Cement is a single use, sterile medical device provided in doses of 40g.

The package contains a 40g packet of powder sterilized by gamma ray and a blister pack sterilized by ethylene oxide containing a 15.7ml vial of sterile liquid that is sterilized by filtration.

Component Formulation

Liquid component	15.7 ml vial
Methylmethacrylate	98.20% w/w
N-N Dimethyl-p-Toluidine	1.80% w/w
Hydroquinone	75 ppm
Powder component	40g packet
Polymethylmethacrylate	82.78% w/w
Barium Sulphate	10.00% w/w
Benzoyl Peroxide	3.00% w/w
Gentamicin sulphate	4.22% w/w*



For Internal Use Only

*Equivalent to 1g (1.0 M.I.U.), 2.5% gentamicin base in 40g unit.

INDICATIONS FOR USE

UNITE® AB Bone Cement is indicated for the fixation of prostheses to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

CONTRAINDICATIONS

UNITE® AB Bone Cement is contraindicated in primary orthopaedic musculoskeletal surgical procedures.

UNITE® AB Bone Cement is contraindicated in patients who are allergic or sensitive to any of its components, including gentamicin sulphate. If the patient has a history of hypersensitivity or