UNITE® AB Bone Cement is contraindicated in the presence of active or incompletely treated infection, at the site where the bone cement is to be applied. In patients with a history of hypersensitivity or allergy to any of the components of UNITE® AB Bone Cement, the use of this product is contraindicated. UNITE® AB Bone Cement provides the fixation of a prosthesis to the anatomy/bone, and its components, including gentamicin sulphate. If the patient has a history of hypersensitivity or allergy to any of the components of UNITE® AB Bone Cement, the use of this product is contraindicated.

**ADVERSE EFFECTS**

**Local reactions**
- Pain
- Swelling
- Redness
- Histamine release

**Systemic reactions**
- Hemorrhage
- Hematomas
- Necrosis
- Necrosis of the entire prosthesis
- Fibrin deposits

**Serious reactions**
- Severe allergic reactions
- Anaphylactic reactions
- Cardiac arrest
- Myocardial infarct
- Cerebrovascular incidents
- Local neuropathy
- Dysuria

**Miscellaneous reactions**
- Nephrotic syndrome
- Proteinuria
- Coagulopathy
- Thrombocytopenia
- Leukocytosis
- Anemia
- Granulocytopenia
- Fever
- Exfoliative dermatitis
- Itching
- Urticaria
- Vomiting
- Diarrhea
- Nausea
- Headache

**Co-administration notes**
- There also appears to be a synergistic effect of loop diuretics, such as furosemide, and gentamicin sulphate. If the patient has a history of renal impairment who are treated for prolonged periods or with higher doses than usually prescribed, additional monitoring of renal function may be indicated.

**Gentamicin sulphate**
- Aminoglycosides antibiotics cross the placenta.
- Several reports of total irreversible bilateral congenital deafness in children whose mother administered to a pregnant woman. Aminoglycosides antibiotics cross the placenta.
- Neurotoxicity primary in patients receiving prolonged therapy or high doses, in those given previous exposure to gentamicin. Aminoglycosides (all) have the potential to produce reversible and irreversible vestibular, cochlear and renal toxicity.
- Neurotoxicity typically irreversible and is brought on initially by diminution of high-tone acuity. Gentamicin sulphate is an aminoglycoside antibiotic derived from the actinomycete genus Streptomyces. The aminoglycosides are a group of structurally related antibiotics that act on bacterial ribosomal RNA. Aminoglycosides have limited allergenic potential; cross-sensitivity between aminoglycosides is rare.

**Techniques**

**Step 1**
- Never change the ratio between liquid and solid components. Do not resterilize and/or reuse the device as it is designed for single-use.

**Step 2**
- Collect the cement from the container and roll it with your fingers until the cement stops sticking to the glove after the loading time. Collect the cement from the container and roll it with your fingers until the cement stops sticking to the glove after the loading time.

**Step 3**
- The mixture must be left to rest once the powder has been mixed with the liquid. The mixture must rest until its viscosity increases and it no longer runs when the container is tipped. The mixture must be left to rest once the powder has been mixed with the liquid. The mixture must rest until its viscosity increases and it no longer runs when the container is tipped.

**Step 4**
- The cement must be inserted into the bone cavity at this time and be well compressed with the body weight. The cement flow must be kept as consistent as possible as this avoids the inclusion of possible air bubbles. The cement must be inserted into the bone cavity at this time and be well compressed with the body weight. The cement flow must be kept as consistent as possible as this avoids the inclusion of possible air bubbles.

**Step 5**
- The prosthesis can be inserted once the cement has been placed within the cavity. Postoperative care should be performed to ensure the cement has hardened. The prosthesis can be inserted once the cement has been placed within the cavity. Postoperative care should be performed to ensure the cement has hardened.

**Temperature effects on preparation and application timing of UNITE® AB Bone Cement**

The temperature of the storage and of the operative area influences the preparation and application of the cement. The temperature effect on cement setting time was evaluated with a laboratory test. A graph on setting time according to temperature is shown below for ease of reference. The data provided was obtained in controlled environmental and storage conditions subjected to standard deviation.

In addition to temperature and humidity, different factors can alter the cement's setting time. These include the mixing process (speed, use of mixer), the thoroughness of mixing, the usage of the entire liquids and solids, the addition of external substances inside the cement such as saline, solution, blood etc., and the pre-heating of the prosthesis component itself.

Manual application is the most effective and recommended for the application of UNITE® AB Bone Cement. The cement must be inserted into the bone cavity at this time and be well compressed with the body weight. The cement flow must be kept as consistent as possible as this avoids the inclusion of possible air bubbles. Postoperative care should be performed to ensure the cement has hardened. Excess cement should be removed prior to hardening. Hardening time of the cement depends on the temperature, type of cement, humidity and the amount of manipulation. Caution: Adjuvant of the prosthesis should be completed as quickly as possible as the temperature of the host bone cavity accelerates cement polymerization.

**Handing**

Gentamicin sulphate is an aminoglycoside antibiotic derived from the actinomycete genus Streptomyces. The aminoglycosides are a group of structurally related antibiotics that act on bacterial ribosomal RNA. Aminoglycosides have limited allergenic potential; cross-sensitivity between aminoglycosides is rare.

**Consult**

Gentamicin sulphate is an aminoglycoside antibiotic derived from the actinomycete genus Streptomyces. The aminoglycosides are a group of structurally related antibiotics that act on bacterial ribosomal RNA. Aminoglycosides have limited allergenic potential; cross-sensitivity between aminoglycosides is rare.

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**INFORMATION**

For further product information, please contact Customer Service.
serious local reactions to antibiotics, the use of any other antibiotics may also be contraindicated due to the known cross-reactivity of patients to drugs in this class.

AB Bone Cement provides the fixation of a prosthesis to the anatomy/bone, and its components, including gentamicin. If the patient has a history of hypersensitivity or intolerance to gentamicin or any of its components, AB Bone Cement is contraindicated.

PRECAUTIONS DURING PREGNANCY, BREAST-FEEDING AND IN CHILDREN

In the event gentamicin bone cement is used during pregnancy or if the patient becomes pregnant while gentamicin bone cement is in use, she should be notified of the possible dangers associated with the use of the product. Gentamicin bone cement is indicated for use in osteolysis young patients only when it is assumed that saving the joint through other means can be avoided; the once-daily regimens are just as safe as or safer than multiple-dose regimens.

Adverse effects on auditory and vestibular branches of the eighth nerve have been found, including neuritis, deafness, dizziness, tinnitus, vertigo, hearing loss, and deafness. Ongoing ototoxic damage can occur. Clinical and animal studies have been conducted to compare the nephrotoxic potential of tobramycin and gentamicin. In some of these studies, tobramycin caused nephrotoxicity significantly less frequently than gentamicin. In other studies, no significant difference in incidence and severity of nephrotoxicity between tobramycin and gentamicin was shown.

Aminoglycosides (all) have the potential to produce reversible and irreversible vestibular, cochlear and renal toxicity. Neuromuscular blockage or respiratory paralysis can occur, more commonly in patients with previous exposure to gentamicin. Anaphylaxis is not a common event but has been reported to occur in patients with documented history of renal impairment who are treated for prolonged periods or with higher doses than those suggested. Neurologic effects that may occur in patients with initial normal renal function include altered sensorium, peripheral neuropathy, and encephalopathy. Typical symptoms are confusion, disorientation, memory impairment, hyperesthesia, and hyperreflexia. Since the onset of these effects may be delayed, patients should be observed for signs of neurologic impairment for at least 7 days. Renal function changes, as shown by increased serum creatinine and blood urea nitrogen levels, and decreased creatinine clearance, have been observed in patients treated with gentamicin. These changes may be reversible if gentamicin is stopped promptly. Adverse effects that may occur during therapy with an ototoxic drug, and those suffering from dehydration. Symptoms of nephrotoxicity may manifest after the conclusion of therapy and may be masked by concomitant usage of diuretics. Gentamicin bone cement is indicated for use in osteolysis young patients only when it is assumed that saving the joint through other means can be avoided; the once-daily regimens are just as safe as or safer than multiple-dose regimens.

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Additional reported adverse effects possibly related to gentamicin include: rash, dermatitis, pruritus, skin changes, rashes, urticaria, alopecia, and pruritus. Aminoglycosides (all) have the potential to produce irreversible and reversible vestibular, cochlear and renal toxicity. Gentamicin bone cement is indicated for use in osteolysis young patients only when it is assumed that saving the joint through other means can be avoided; the once-daily regimens are just as safe as or safer than multiple-dose regimens.

PHARMACOKINETICS

Gentamicin is rapidly bactericidal. It acts primarily by inhibiting protein synthesis and leading to increased sensitivity of bacterial cell membrane permeability, progressive depletion of the cell envelope as well as other vital processes and cell death.

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serious toxic reactions to aminoglycosides, the use of any other aminoglycosides may also be contraindicated due to the known cross-sensitivity of patients to drugs in this class. UNITE Bone Cement is not to be used in patients with a history of hypersensitivity or allergy to gentamicin or any of its components, including gentamicin sulphate. If the patient has a history of hypersensitivity or allergy to any of these drugs, UNITE Bone Cement is contraindicated.

### CONTRAINDICATIONS

- **Known hypersensitivity or allergy to gentamicin or any of its components, including gentamicin sulphate.**
- **Hemorrhagic diathesis, thromboembolic disease, current use of antithrombotic or antiplatelet agents, or history of significant cardiovascular disease.**
- **Obstructive lung disease, severe emphysema, or severe cor pulmonale.**
- **Hepatic or renal impairment.**
- **Pregnancy or lactation.**
- **Children younger than 12 years of age.**

### PRECAUTIONS DURING PREGNANCY, BREAST-FEEDING AND IN CHILDREN

- **Children younger than 12 years of age:** The safety and efficacy of UNITE Bone Cement in children have not been established. Therefore, it is not recommended for use in children.
- **Pregnancy:** UNITE Bone Cement is not recommended for use during pregnancy, as the potential risk to the fetus outweighs any potential benefit.
- **Breast-feeding:** The presence of gentamicin sulphate in breast milk is unknown. Therefore, it is not recommended for use during breastfeeding.

### PHARMACODYNAMICS

- **Mechanism of action:** UNITE Bone Cement provides the fixation of a prosthesis to the anatomy/bone, and its components, including gentamicin sulphate. If the patient has a history of hypersensitivity or allergy to gentamicin or any of its components, including gentamicin sulphate, UNITE Bone Cement is contraindicated.

### Setting Time - Temperature Chart

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<tr>
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</tbody>
</table>

### INFORMATION

- **Store at a temperature of 15°C to 30°C.**
- **Do not freeze.**
- **Expiration date:** The expiration date is 6 years from the date of manufacture.
- **Packaging:** The package contains a 40g packet of powder sterilized by gamma ray and a blister pack containing a syringe and plunger.

### RESTING TIME

- **Step 1:** ASSEMBLE
- **Step 2:** OBTAIN
- **Step 3:** ASSEMBLE
- **Step 4:** INSERT
- **Step 5:** ADD
- **Step 6:** APPLICATION
- **Step 7:** APPLY
- **Step 8:** MANIPULATE
- **Step 9:** HARDEN
- **Step 10:** HOLD

### WARNING:

- **Do not resterilize and/or reuse the device as it is designed for single-use on a single patient. Never divide the product into two or more portions, in order to use it for other clinical applications or at different times. This reutilization may lead to an error in the dosage of the drug and a malfunction of the device with serious risks for the patient's well-being. Residues of a previous use may contaminate the next use.**

### ADVERSE EFFECTS

- **Nausea, vomiting, anorexia, headache, dizziness, weakness, tinnitus, vertigo, paresthesia, diarrhea, nausea, fever, rash, alopecia, myalgia, arthralgia, dysuria, and epistaxis.**

### TOLERANCE +

- **Mild transient pale color of the skin and mucous membranes.**
- **Mild transient heart rate increase.**
- **Mild transient increase in body temperature.**

###マイクロバイオラシス

- **Microbiota:**
- **Gentamicin is rapidly bactericidal. It acts primarily by inhibiting protein synthesis and leading to increased cell turnover and decreased or absent growth.**

### 収束

- **Gentamicin is rapidly bactericidal. It acts primarily by inhibiting protein synthesis and leading to increased cell turnover and decreased or absent growth.**

### 起源

- **Gentamicin is rapidly bactericidal. It acts primarily by inhibiting protein synthesis and leading to increased cell turnover and decreased or absent growth.**
serious local reactions to antibiotics, the use of any other antibiotics may also be contraindicated due to the known cross-sensitivity of patients to this class.

UNITE™ AB Bone Cement is contraindicated in the presence of active or incompletely treated infections, at the site where the bone cement is to be applied.

UNITE™ AB Bone Cement is contraindicated where the loss of muscular or neuromuscular compression in the affected limb would render the surgical procedure unjustifiable.

Serious toxic reactions to aminoglycosides, the use of any other aminoglycosides may also be contraindicated due to the known cross-sensitivity of patients to drugs in this class.

INDICATIONS FOR USE
UNITE™ is manufactured for OsteoRemedies, LLC and tobramycin sulfate share similar ototoxic potential.

Typically irreversible and is brought on initially by diminution of high-tone acuity. Gentamicin and tobramycin sulfate share similar ototoxic potential. Aminoglycosides (all) have the potential to produce reversible and irreversible vestibular, neurological and renal toxicity.

Microbiology Overview
Gentamicin is an aminoglycoside antibiotic derived from the actinomycete Micromonospora purpurea. The molecular weight is 643.5. The product contains no lactose, phenol, milk products, soya products, starch, sugar, artificial colorants or flavorings.

Pharmacology
Mechanisms of action
Gentamicin is rapidly bactericidal. It acts primarily by inhibiting protein synthesis and leading to increasing of ribosomes leading to cellular membrane permeability, progressive depletion of the cell envelope as well as other vital processes and cell death.

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AB Bone Cement must be considered carefully in the presence of myasthenia gravis. Aminoglycosides have limited allergenic potential; neuromuscular blockage or respiratory paralysis can occur, more commonly in patients with Parkinson’s disease or myasthenia gravis. Aminoglycosides have limited allergenic potential; both anaphylactic and non-anaphylactic reactions, which include fever, skin rash, eosinophilia, etc., have been noted.

Additional reported negative effects possibly related to gentamicin include: rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, fever, chills, nausea, weakness, severe pruritis, vomiting, diarrhea, anorexia, anemia, leukopenia, neutropenia, thrombocytopenia, leukocytosis, eosinophilia, and pancreatitis. Use in women: The potential for aminoglycosides to cause fetal harm when administered to a pregnant woman. Aminoglycosides antibiotics cross the placenta. Several reports of fatal irreversible bilateral congenital deafness in children whose mothers received streptomycin during pregnancy have been reported. Use in children: The use in skeletal young patients only when it is assumed that saving the joint through other forms of intervention is not possible.

In the event gentamicin bone cement is used during pregnancy or if the patient becomes pregnant while gentamicin bone cement is in use, she should be notified of the possible dangers to the fetus. Women of childbearing potential should consult the benefits and dangers associated with the use of the product. Gentamicin bone cement is indicated for use in osteotomies, young patients only when it is assured that the joint is going to be left in situ. Use in patients with active infections: The use of aminoglycoside bone cement is not recommended in patients with active infections or withknown skin lesions. As aminoglycosides may penetrate into bone, care must be taken to ensure that the bone cement does not come into contact with infected tissue.

Use in patients with impaired renal function: The use of aminoglycoside bone cement is not recommended in patients with impaired renal function. As aminoglycosides may penetrate into bone, care must be taken to ensure that the bone cement does not come into contact with infected tissue.

Gentamicin sulphate is an aminoglycoside antibiotic derived from the actinomycete Micrococcus luteus. The molecular weight is 946.5. The product contains no preservative or sodium benzoate. Gentamicin sulphate is a complex of the gentamicins C1, C1a, C1b, and C2a illustrated below.

Microbiology and Mechanisms of Action

Gentamicin is rapidly bactericidal. It acts primarily by inhibiting protein synthesis and leading to increasing of cell lysis leading to the cell membrane permeabilization, progressive depletion of the cell envelope as well as other vital processes and cell death.
Antibiotic activity

Gentamicin activity is primarily directed against aerobic, gram-negative bacilli. The activity is greatest against the more sensitive species of Pseudomonas, coliforms, and enteric gram-negative bacilli. Gentamicin is active in vitro against more than 90% of S. aureus and 75% of S. epidermidis. Gentamicin has been shown to be active against most gram-positive organisms following 12 hours of incubation in broth and in clinical infection.

Most common susceptible pathogens

Gram positive bacteria

- Staphylococcus aureus
- Streptococcus pneumoniae
- Streptococcus faecalis

Gram negative bacteria

- Escherichia coli
- Enterobacter sakazakii
- Klebsiella pneumoniae
- Pseudomonas aeruginosa

AB Bone Cement® should not come into contact with patient’s skin and mucous membranes. Do not come into contact with tissues, synovial fluid, cerebrospinal fluid, or any other body cavities. Formalin, benzalkonium chloride and glycol are found in AB Bone Cement®. Formaldehyde and benzalkonium chloride have been shown to cause necrosis of connective tissue.

If any form of infection should arise following surgery, patients are instructed to inform their treating physician immediately.

Aminoglycosides

Aminoglycosides are a group of antibiotics that have a broad antibacterial spectrum and are bactericidal. The family includes streptomycin, gentamicin, tobramycin, amikacin, and netilmicin. The aminoglycosides are closely related and have a similar mode of action. Aminoglycosides have a variety of antibacterial spectra, each with unique susceptibility profiles. They are active mainly against gram-negative bacilli and some gram-positive cocci. Aminoglycoside toxicity is related to the rate of administration. Aminoglycosides are known to cause hearing loss and renal damage, both of which are dose-related.

Bacteria may be resistant to the antimicrobial activity of the aminoglycosides because of failure of penetration of the antibiotic, low efficacy of the drug for the bacterial isolate, or inactivation of the drug by bacterial enzymes. Drug inactivation is by far the most important explanation for the acquired intraocular resistance to aminoglycosides that is encountered in clinical practice. Cross-resistance between aminoglycosides may occur.

The antibiotic activity of the aminoglycosides is rapidly excreted in the urine after intravenous administration. Only a small fraction of a parenteral dose (e.g. in dog) is excreted unchanged during the first 24 hours, with most of the remainder being excreted during the next 2 days. Aminoglycosides are removed from the body by glomerular filtration and tubular secretion. Therefore, in patients with reduced renal function, the serum levels of aminoglycosides may be elevated. In patients with severe renal impairment, the serum levels of aminoglycosides may be so high as to result in toxicity. In such patients, it is recommended that the doses be reduced accordingly.

In some cases events defined as “bone implantation syndromes” (BIS) may occur which are characterized by a number of clinical features that include hypotension, hypovolemia, hypothermia, increased pulmonary pressures (PVR and CO), and hypoxemia. Overall mortality for the patients is related to the severity of the event. The role of aminoglycosides in the prevention or treatment of BIS is not clear. It is recommended that aminoglycosides be used only when absolutely necessary.

In patients with renal impairment, the renal excretion of aminoglycosides is reduced, and the half-life of the drug is prolonged. In patients with severe renal impairment, the half-life of aminoglycosides may be doubled. In such patients, the dose of aminoglycoside should be reduced accordingly.

In patients with normal renal function, the normal daily dose of aminoglycoside may be given as a single intramuscular injection. In patients with moderate renal impairment, the daily dose of aminoglycoside may be given as two intramuscular injections. In patients with severe renal impairment, the daily dose of aminoglycoside may be given as three intramuscular injections. In patients with anuric renal failure, the daily dose of aminoglycoside may be given as four intramuscular injections.

Dosage and Administration

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Antibacterial activity

Gentamicin activity is primarily directed against aerobe gram-negative bacilli. The antibiotic action is most rapidly expressed against facultative or obligate anaerobes of the genus Bacteroides, and in clinical infections.

Most common susceptible pathogens

Gram positive bacteria: Staphylococcus epidermidis, Staphylococcus aureus, Streptococcus faecalis, Enterococcus faecium

Gram negative bacteria:

- Aerobacter aerogenes
- Citrobacter freundii
- Enterobacter cloacae
- Escherichia coli
- Klebsiella spp.
- Proteus mirabilis
- Proteus vulgaris
- Pseudomonas aeruginosa

In vitro, the antibiotics are absorbed rapidly from intramuscular sites of injection. Peak concentrations in plasma occur after 30 to 60 minutes and are similar to those observed 30 minutes after an intravenous administration. The t1/2 of amikacin is approximately 6 hours; of streptomycin, 30 minutes; and of gentamicin, 2 to 3 hours. Therefore, an equal dose of antibiotic should be given every 6 to 8 hours to maintain constant plasma levels. The rate of decline of the aminoglycosides is concentration dependent. The aminoglycosides are only partially absorbed from neonatal enterococci demonstrate in vitro resistance, some strains in the group are susceptible. (e.g. S. faecalis). In vitro studies have shown that the aminoglycosides combined with an antibiotic interfering with cell wall synthesis (e.g. penicillin, vancomycin) affects some enterococcal strains synergistically, resulting in more-bactericidal effect. The effect of this interaction lowers the minimal inhibitory concentration of the antibiotics, increases the killing effect of these classes of antibiotics in enterococci susceptible to antibiotics and enterococci simultaneously resistant to antibiotics in enterococci and streptococci at concentrations which can be achieved clinically only when other antibiotics (e.g. penicillin, vancomycin) affects some enterococcal strains synergistically, resulting in more-bactericidal effect. The effect of this interaction lowers the minimal inhibitory concentration of the antibiotics, increases the killing effect of these classes of antibiotics in enterococci susceptible to antibiotics and enterococci simultaneously resistant to antibiotics.

Gentamicin, tobramycin, amikacin, tobramycin, netilmicin, and amikacin are used in the treatment of infections caused by susceptible strains of aerobic gram-negative bacilli and clinically important strains of enterococci and streptococci. Although most strains of enterococci demonstrate in vitro resistance, some strains in the group are susceptible. (e.g. S. faecalis). In vitro studies have shown that the aminoglycosides combined with an antibiotic interfering with cell wall synthesis (e.g. penicillin, vancomycin) affects some enterococcal strains synergistically, resulting in more-bactericidal effect. The effect of this interaction lowers the minimal inhibitory concentration of the antibiotics, increases the killing effect of these classes of antibiotics in enterococci susceptible to antibiotics and enterococci simultaneously resistant to antibiotics.

In order to reduce the risk of induction of blood and debris within the cement, and of marrow contamination, the bone cement needed based on the clinical application and needs. Diuretics are rarely a source of vestibulotoxicity and may be a source of hearing impairment. The dual use of gentamicin and neuromuscular blocking agents can cause respiratory paralysis/neuromuscular blockade and may be reversed by calcium salts. The dual use of gentamicin and neuromuscular blocking agents can cause respiratory paralysis/neuromuscular blockade and may be reversed by calcium salts. The dual use of gentamicin and neuromuscular blocking agents can cause respiratory paralysis/neuromuscular blockade and may be reversed by calcium salts.
Microbial resistance

Bacteria may be resistant to the antibiotic resistance of the aminoglycosides because of failure of penetration of the antibiotic, low efficacy of the drug for the bacterial clientele, or inactivation of the drug by microbial enzymes. Drug inactivation is by far the most important explanation for the acquired microbial resistance to aminoglycosides that is encountered in clinical practice. Cross-resistance between aminoglycosides may occur.

Absorption

All of the aminoglycosides are absorbed rapidly from intramuscular sites of injection. Peak concentrations in plasma occur within 30 to 90 minutes and are similar to those observed 30 to 60 minutes after oral administration. Streptomycin, gentamicin, kanamycin, and neomycin are the aminoglycosides that are used most often. Other aminoglycosides that are injected by intramuscular injection include amikacin, tetracycline, and tetracycline. Absorption of an equal dose over a 30-minute period in critically ill patients, especially those in shock, absorption of drug may be reduced from 40% to 60% of the administered dose. Drug absorption varies with poor perfusion. Therefore and therefore are very poorly absorbed from the gastrointestinal tract.

Bone cements reach temperatures higher than physiological temperatures when the surgeon can release the prosthesis. Achievement of this state is determined by the increase in temperature of the cement. The components are mixed. Viscosity increases rapidly to form a mass which securely adheres the gloved hand until the cement has formed into the consistency of dough (roughly 1-2 minutes latex or rubber gloves. UNITE® AB Bone Cement should not come into contact with the operative area until the cement has hardened. The operative area must be correctly ventilated as the liquid component is both flammable and toxic if inhaled. Exposure to the concentrated vapors of liquid monomer. This exposure may cause irritation of the conjunctivae, conjunctivitis, and just as effective. Toxicity results from inhalation of drug in the eye or ear canaliculi. The combination of penicillin G and gentamicin results in a synergistic bactericidal function that may not be evident in the results of routine screening tests, such as BUN and creatinine function (creatinine clearance less than or equal to 20 ml/min).

Diuretics are rarely a source of vestibulotoxicity and may be a source of hearing impairment. The dual use of gentamicin and neurotoxic blocking agents can cause respiratory paralysis/near- total blockade and may be reversed by calcium salts.

CIRCULATION

In order to reduce the risk of induction of blood and debris within the cement, and of marrow aspiration in the prosthesis, the cement must be properlyingested with Bipolar saline solutions and dried prior to the application of bone cement. It is critical the maintenance of the prosthesis with manual pressure until the end of the polymerization phase, while the cement hardens; this is important to avoid ideal implantation.

Antibacterial activity

Gentamicin activity is primarily directed against aerobic, gram-negative bacilli. The antibiotic is not effective against anaerobic bacteria, Mycobacterium, Nocardia, and Actinomyces. Gentamicin decreases and reduces the microbial load before and during the surgical procedure.

The cementation process.

Step 1

Open the package and remove internal items. Place the powder packet and vial of liquid acetabular or femoral cement implantation, insertion of the prosthesis or joint reduction preparation stages. Prior to using UNITE® AB Bone Cement it is strongly advised to make averagedose studies from linearity. Analysis of variance was used to analyze the data.

The antibiotic activity of the aminoglycosides is that they increase membrane leakage. Aminoglycosides have a very low affinity for bacterial cell walls and all bacteria contain cell walls. The aminoglycosides are a clinically important group of antibiotics that have a broad antibacterial activity. The aminoglycosides are effective against a wide range of bacterial species. They are active against aerobic and anaerobic bacteria, as well as against gram-positive and gram-negative bacteria. The aminoglycosides are active against most strains of the following organisms both in vitro and in patients with bone cement.
Microbial resistance

Bacteria may be resistant to the antibiotic activity of the aminoglycosides because of failure of permeation of the antibiotic, low activity of the drug for the bacterial strain, or inactivation of the drug by microbial enzymes. Drug inactivation is by far the most important explanation for the acquired microbial resistance to aminoglycosides that is encountered in clinical practice. Cross-resistance between aminoglycosides may occur.

Absorption

All the aminoglycosides are absorbed rapidly from intramuscular sites of injection. Peak concentrations in plasma occur within 30 to 60 minutes and are similar to those observed 30 minutes after an oral dose. Aminoglycosides are concentrated in the urine, and the overall rate of absorption of an equal dose over a 30-minute period is critically related to them; absorption of drug may be reduced from syringes or vials by the action of bacterial enzymes. This explains the high potencies and therefore are very poorly absorbed from the gastrointestinal tract.

Drug effects and toxicity

The drug effects for gentamicin, including the mechanism of actions and antibacterial spectrum, have already been discussed in the previous paragraphs. Gentamicin containing bone cements have not been clinically shown to be toxic against the organisms of indicated above.

Aminoglycosides

Gentamicin, streptomycin, kanamycin, tobramycin, netilmicin, and amikacin are the aminoglycosides that are clinically available. The aminoglycosides are a clinically important group of antibiotics that have a broad antibac-

CAUTION: NEVER add other substances or foreign bodies to UNITE® AB Bone Cement.

Cautions: Bone cement reaches higher temperatures than physiological temperatures during the polymerization reaction. Polymerization of the bone cement is an exothermic reaction (and may cause burns). Burn injuries may occur by contact with the bone cement, bone cement components, or by warming in the hands. The cement may melt and cause damage or tissue burn. The bone cement, bone cement components, or any liquid used to mix the bone cement may cause tissue damage. Contact with bone cement may cause allergic reactions to susceptible individuals.
Antibacterial activity

Gentamicin should be used in clinically significant aerobic and anaerobic infections. It is generally good practice to administer a second agent, preferably a penicillin, because the organism may have a tendency to develop resistance.

Microbial resistance

Bacteria may be resistant to the antibacterial activity of the aminoglycoside because of failure of permeation of the antibiotic, low activity of the drug for the bacterial membrane, or inactivation of the drug by microbial enzymes. Drug inactivation is for the most part by nonenzymatic chemical reactions and it is not generally reversible. The aminoglycosides are affected by high pH, such as is present in urine and other body fluids with low protein content.

Aminoglycoside antibiotics are a clinically important group of antibiotics that have a broad antibacterial spectrum and are important in the treatment of serious infections. They are bactericidal and are effective in both aerobic and anaerobic infections. The aminoglycosides such as streptomycin are completely inactivated by human enzymes and there is no report of development of resistance in humans.

CLINICAL USE

The use of drugs depending on the clinical application and needs. The bone cement needed based on the clinical application and needs. This is particularly important for the treatment of bone cement.

CEMENT PREPARATION PRECAUTIONS

Do not use the after the expiration date since the effectiveness of the device may be compromised.

Ensure the inner packages and components are unbroken. Powder should be completely mixed for at least 30 seconds before use. The contents within the external pack should be used as a low viscosity liquid.

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Prosthesis to the host site. Components are mixed. Viscosity increases rapidly to form a mass which securely adheres the bone cement. The consistency of the bone cement changes in just a few minutes once the two components are mixed. This means that an equal dose over a 30-minute period. In critically ill patients, especially those in shock, absorption of drug may be reduced from the gastrointestinal tract. The absorption of drugs is highly variable and therefore are very poorly absorbed into the gastrointestinal tract.

Drug interactions and testing for antibiotics are emphasized.

If any form of infection should arise following surgery, patients are instructed to inform their surgeon. The surgical team perform trials prior to use in patients under the same environmental and temperature, and are best determined by the surgeon. It is recommended that the prosthesis should be covered by a uniform coating of bone cement.

The bone surface must be dried with gauze and/or suction catheters before and during the cementation procedure. Any fluid left on the bone may prevent the cement from adhering properly. Aminoglycosides have a biological half-life of 2 to 3 hours in patients with normal renal function. Renal clearance of aminoglycosides is dependent on the concentration of the drug in plasma. The concentration in plasma is highest in the proximal convoluted tubule. Renal excretion of aminoglycosides is a function of glomerular filtration. To achieve therapeutic concentrations of aminoglycosides in ocular fluids is so poor that effective therapy of bacterial endophthalmitis in vitro. Bactericidal effects within the bacterial cell but principally they inhibit protein synthesis. Another important function of the aminoglycosides is that they increase membrane leakage. Aminoglycosides have a little activity against most gram-positive bacteria, including Streptococcus pyogenes, Staphylococcus aureus and enterococci. The combination of penicillin G and aminoglycosides results in a synergistic effect in vitro against certain strains of Enterococcus faecalis. However, this combination is not synergistic against other closely related organisms (e.g., S. Pseudintermedius). Susceptible and effective antibiotics for synergistic synergists are emphasized.
Antibacterial activity

Gentamicin activity is primarily directed against aerobic, gram-negative bacilli. The antibiotic most commonly used is gentamicin. Gentamicin is active against sensitive strains of enterococci and staphylococci at concentrations which can be achieved clinically only when combined with a penicillin. Gentamicin is active in vitro against more than 90% of strains of S. aureus and 75% of S. epidermidis. Gentamicin has been shown to be active against most strains of Pseudomonas aeruginosa, including more than 90% of those isolated in clinical practice. Most common susceptible pathogens

Gram positive bacteria

S. aureus, Staphylococcus pyogenes, Staphylococcus pneumoniae, Streptococcus faecalis, Listeria monocytogenes

Gram negative bacteria

Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Providencia rettgeri, Serratia, Shigella, Ps. aeruginosa, Pseudomonas severtorum

The drug factors for gentamicin, including its mechanism of action and antibacterial activity, have not been completely defined. AB Bone Cement in patients with renal or vestibular/auditory compromise should be used. Simultaneous or sequential use of aminoglycosides (i.e. IV antibiotics, antibiotic beads prior to surgery, monitoring of trough serum concentrations should be performed on the patients. Achievement of this state is determined by the increase in temperature of the cement. The cure is complete once the cement is mixed. Viscosity increases rapidly to form a mass which securely adheres the bone. In the case of vertebral and auditory prostheses, the surgeon should be prepared and familiar with the application, properties, and handling of UNITE AB Bone Cement to ensure a successful procedure. Curing time and temperature, and are best determined by the surgeon. It is recommended that the operative area must be correctly ventilated as the liquid component is both flammable and toxic. Different lot numbers of UNITE AB Bone Cement may be used in tandem when mixed properly.

PREFERENCES

AB Bone Cement liquid is a light purple liquid solvent. Do not mix out into contact with latex or rubber gloves. UNITE AB Bone Cement should not come into contact with the glass or the cement has formed into the consistency of dough (roughly 2-12 minutes). If the fluid becomes visible or changes color, it should be discarded.

The use of gentamicin, other aminoglycosides have been administered to the patient prior to surgery, monitoring of trough serum concentrations should be performed on the patient on the day before the operation. If serum concentrations exceed 1µg/ml gentamicin, tobramycin, or neomycin, the aminoglycoside antibiotic may be administered in the formulation are used. Simultaneous or sequential use of aminoglycosides (i.e. IV antibiotic, antibiotic beads incorporated bone cement) in patients with renal or vestibular/auditory compromise should be avoided. Gentamicin bone cement should not be used in patients with impaired renal function (creatinine clearance less than or equal to 20 ml/min).

Monitoring

Potential gentamicin bone cement should be periodically monitored with peak and trough levels of the antibiotic, serum electrolytes, serum renal function, and urinalysis. It is recommended to be used by the entire surgical team in the operating room. The aminoglycosides are excreted almost entirely by glomerular filtration, and concentrations of aminoglycosides in endolymph and perilymph of the inner ear; this is important to ensure ideal implantation.

In some cases events defined as "bone implantation syndrome" (BIS) may occur which are characterized by a number of clinical features that include hypotension, hypoxia, hypothermia, and changes in renal function which usually occurs in one of the stages in the surgical procedure. The most frequent clinical signs are divided into two phases: the preoperative phase and the postoperative phase (Doroshow et al., 2004, 2007). Patients with severe renal impairment may be at risk for the development of these drug in patients with impaired renal function. Aminoglycosides are removed from the body by the renal route and are not metabolized.No other cationic antimicrobial drug with a similar side effect profile is available.

Bibliography


GENERAL PRECAUTIONS

- Potentially to be implanted must be compatible with the use of bone cement.
- The surface of the bone cement must be frictionless.

Cement

- Do not use after the expiration date since the effectiveness of the device may be compromised.
- Ensure the inner packages and components are undamaged. Powder should be completely dry prior to mixing and the cement should be mixed within 30 minutes of mixing. Lower temperatures of the environment may lead to an increase in the working time of the cement. The powder is a sterile product that must be stored at a temperature of 23°C ± 5°C for 24 hours before mixing.

Cement APPLICATION PRECAUTIONS

Clinical studies show the need to maintain strict aseptic surgical procedures. Some deep infections may appear after surgical intervention. In order to reduce the risk of infection of blood and debris within the cement, and of marrow and blood aspiration, bone cement may be properly impregnated with Biotin 500 mg/ml solution and dried prior to the application of bone cement. The drug should be administered as soon as possible after surgery. Cross-resistance between aminoglycosides may occur. It is strongly advised to make the most of the concentration in the vascular system, the bone cavity must be properly irrigated with Ringer or lactate solution by the surgeon. In order to reduce the risk of inclusion of blood and debris within the cement, and of marrow aspiration, bone cement may be properly impregnated with Biotin 500 mg/ml solution and dried prior to the application of bone cement. The powder should be completely dry prior to mixing and the cement should be mixed within 30 minutes of mixing. Lower temperatures of the environment may lead to an increase in the working time of the cement. The powder is a sterile product that must be stored at a temperature of 23°C ± 5°C for 24 hours before mixing.

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Antibacterial activity
Gentamicin activity is primarily directed against aerobic, gram-negative bacteria. The agent can be most generally used for the treatment of infections caused by such bacteria. However, it is effective against a wide range of aerobic and anaerobic gram-negative pathogens, some of which are highly resistant to other antibiotics. Gentamicin is active in vitro against many of the Enterobacteriaceae. It is effective against S. aureus and S. pyogenes but less active against other streptococci. The aminoglycosides are active against many species of clostridia but only poorly active against staphylococci and streptococci. Gentamicin is active in vitro against many species of the Enterobacteriaceae, including most strains of Enterobacter, Escherichia coli, Klebsiella, Proteus mirabilis, and Serratia marcescens. It is effective against Pseudomonas aeruginosa, the principal cause of nosocomial respiratory tract infections. It is also active against many strains of the genus Staphylococcus, including S. aureus and S. epidermidis. Gentamicin is active against many strains of the genus Enterococcus, including Enterococcus faecalis and Enterococcus faecium. Gentamicin is active against many strains of the genus Citrobacter, including Citrobacter diversus and Citrobacter freundii. Gentamicin is active against many strains of the genus Klebsiella, including Klebsiella pneumoniae and Klebsiella oxytoca. Gentamicin is active against many strains of the genus Proteus, including Proteus mirabilis and Proteus vulgaris.

In vitro activity
Gentamicin has a bactericidal effect against most bacteria. The minimum inhibitory concentration (MIC) is the lowest concentration of an antibiotic that inhibits the growth of a microorganism in vitro. The MIC is usually expressed in micrograms per milliliter (μg/mL). Gentamicin has a relatively broad spectrum of activity, and it is effective against many common causes of bacterial infections. Gentamicin is most active against aerobic gram-negative bacteria, including Enterobacteriaceae such as Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa. It is also active against many species of the genus Staphylococcus, including S. aureus and S. epidermidis. Gentamicin is active against many strains of the genus Enterococcus, including Enterococcus faecalis and Enterococcus faecium. Gentamicin is active against many strains of the genus Citrobacter, including Citrobacter diversus and Citrobacter freundii. Gentamicin is active against many strains of the genus Klebsiella, including Klebsiella pneumoniae and Klebsiella oxytoca. Gentamicin is active against many strains of the genus Proteus, including Proteus mirabilis and Proteus vulgaris.

Microbial resistance
Bacteria may be resistant to the antibacterial activity of the aminoglycosides because of failure of permeation of the antibiotic, low efficacy of the drug for the bacterial strain, or inactivation of the drug by microbial enzymes. Drug inactivation is by far the most important explanation for the acquired microbial resistance to aminoglycosides that is encountered in clinical practice. Cross-resistance between aminoglycosides may occur.

Absorption
All the aminoglycosides are absorbed rapidly from intramuscular sites of injection. Peak concentrations in plasma occur after 30 to 90 minutes and are similar to those observed 30 minutes after intravenous injection. The aminoglycosides are excreted slowly in urine and in biliary excretions. The half-life of an equal dose over a 30-minute period. In critically ill patients, especially those in shock, absorption of drug may be reduced from the site of injection, and this may reduce the peak penetration. Absorption is unaffected by high protein levels and therefore are very poorly absorbed from the gastrointestinal tract.

Common side effects
The drug therapy for gentamicin, including its mechanism of actions and antibacterial spectrum, is beyond the scope of this book. For more information, please see the textbooks in the bibliography. Gentamicin containing bone cements have not been clinically shown to have clinical effects on other antibiotics of the indicated groups above.

Aminoglycosides
Aminoglycosides are a group of naturally occurring antibiotics that have a broad antibacterial spectrum and their action is bactericidal. The family includes streptomycin, gentamicin, tobramycin, amikacin, and netilmicin. The aminoglycosides such as spectinomycin are closely related and have a similar mode of action. Aminoglycosides have a variety of therapeutic indications, including infection of the central nervous system, osteomyelitis, and endocarditis. The aminoglycosides are clinically and functionally related to the aminoglycosides that they have increasing membrane leakage. Aminoglycosides have a little activity against anaerobic bacteria. Aminoglycosides are the most active antibiotics against Pseudomonas aeruginosa. Aminoglycosides are closely related and have a similar mode of action. Aminoglycosides are spectinomycin, which is the most active antibiotics against Pseudomonas aeruginosa. Aminoglycosides are closely related and have a similar mode of action. Aminoglycosides are spectinomycin, which is the most active antibiotics against Pseudomonas aeruginosa. Aminoglycosides are closely related and have a similar mode of action. Aminoglycosides are spectinomycin, which is the most active antibiotics against Pseudomonas aeruginosa.
AB Bone Cement.

CH NH₂

• Local vascular erosion and occlusion
• Hematuria
• Dysuria

ADVERSE EFFECTS

The presence of barium sulphate enables radiopacity.

Serious toxic reactions to aminoglycosides, the use of any other aminoglycosides may also not ensure that recurrence or resistance is avoided.

• Elevated serum gamma-glutamyl-transpeptidase (GGTP) up to 10 days post surgery
• Hematoma-hemorrhage
• Pain and/or loss of function
• Trochanteric bursitis

Additional reported negative effects possibly related to gentamicin include: rash, thrombocytopenia, fever, exfoliative dermatitis, itching, urticaria, vomiting, diarrhea, nausea, headache, nausea, fever, and syncope.

Patient is administered for longer than the recommended dose.

Clinical and animal studies have been conducted to compare the nephrotoxic potential of tobramycin and gentamicin. The incidence of nephrotoxicity between tobramycin and gentamicin was discovered.

PHARMACOLOGY

Gentamicin sulphate is an aminoglycoside antibiotic derived from the actinomycete species of Pseudomonas. The aminoglycosides are cationic poly-O-saccharides that target RNA-dependent protein synthesis.

PHYSICOCHEMICAL PROPERTIES

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 cleaned.

CONTRAINDICATIONS

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 anaphylaxis to aminoglycosides, the use of any other aminoglycosides may also be contraindicated. If the patient has a history of hyperkalemia, hypokalemia, or hypomagnesemia, the use of aminoglycosides may also be contraindicated.

Aminoglycosides are classified as category D agents. They are contraindicated during pregnancy and breastfeeding, as well as in children. It is advised that bone cement should be contraindicated during pregnancy and breastfeeding, as well as in children. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available. It is advised that bone cement should not be used during breast-feeding, and in children are not available.
• Local neuropathy
• Dysuria
• Cardiac arrest

Serious reactions

presence of barium sulphate enables radiopacity.

UNITE

gravis. There may be increased risk of ototoxicity from gentamicin, if other ototoxic drugs

UNITE

be contraindicated due to the known cross-sensitivity of patients to drugs in this class.

®

AB Bone Cement is contraindicated where the loss of musculature or neuromuscular

Component Formulation

Liquid component 15.7 ml vial
Methylmethacrylate 98.20% w/w
Hydroquinone 75 ppm

Powder component 40g packet

*Equivalent to 1g (1.0 M.I.U.), 2,5% gentamicin base in 40g unit.

second stage of a two-stage revision for total joint arthroplasty after the initial infection has

procedures.

• Patients with pre-existing renal damage
• Patients with normal renal function to whom aminoglycosides are administered for longer
dosages of gentamicin sulphate for systemic parenteral administration.

The following adverse reactions have been connected with doses typical of prescribed

Nephrotoxicity

Negative reactions to gentamicin sulphate are not expected at the levels contained within

its components, including gentamicin sulphate. If the patient has a history of hypersensitivity or

infection of surface/deep surgical wound
• Thrombophlebitis

Adverse effects on auditory and vestibular branches of the eighth nerve have been found,

neuromuscular blockage or respiratory paralysis can occur, more commonly in patients with

significantly less frequently than gentamicin. In other studies, no significant difference in

tobramycin and gentamicin. In some of these studies, tobramycin caused nephrotoxicity

and tobramycin sulfate share similar ototoxic potential.

typically irreversible and is brought on initially by diminution of high-tone acuity. Gentamicin

courses of therapy with an ototoxic drug, and those suffering from dehydration. Symptoms

leukocytosis, and eosinophilia.

fever, skin-rashes, eosinophilia, etc., have been noted.

both anaphylaxis and rash are uncommon. Rare hypersensitivity reactions, which include

causing temporary or permanent hearing loss in infants exposed to gentamicin in utero. A

Document version 6.7

PHARMACOLOGY

MICROBIOLOGY OVERVIEW

use in skeletally young patients only when it is assumed that saving the joint through other

dangers to the fetus. Women of childbearing potential should consider the benefits and

received streptomycin during pregnancy have been noted. Issues to mother, fetus, or new

period, bone cement should only be used in critical, life endangering situations. Animal

STORAGE

In addition to temperature and humidity, different factors can alter the cement’s setting time.

Manual application is the most effective and recommended for the application of UNITE

Manual application is the most effective and recommended for the application of UNITE

AB Bone Cement

The cement must be inserted into the bone cavity at this time and be well compressed

too late once the container is tipped

Handing

Remove cement from the container and hold it with your fingers until the cement stops

Caution! Application of the prosthesis should be completed as quickly as possible as the

Caution! Application of the prosthesis should be completed as quickly as possible as the

UNITE® AB Bone Cement

The temperature of the storage and of the operative area influences the preparation and

application of the cement. The temperature’s effect on cement setting time was evaluated

with a laboratory test. A graph on setting time according to temperature is shown below

for ease of reference. The data provided were obtained in controlled environmental and

storage conditions subjected to standard deviation.

In addition to temperature and humidity, different factors can alter the cement’s setting time.

These include mixing process (speed, use of mixers), the freshness of mixing, the usage

of the entire liquids and solids, the addition of external substances inside the container

such as, saline solution, blood etc., and the pre-heating of the prosthesis component itself.

Setting Time - Temperature Chart

SETTING TIME (min.)
28
24
23
22
20
19
16
14
12
10
8
6
4
2
0

Tolerance +

Tolerance -

WARNING:

Never change the ratio between liquid and solid components.

Do not resterilize and/or reuse the device as designed for single-use on a single patient.

Never divide the product into two or more portions, in order to use for other clinical applications or at different times. This repetition may lead to an error in the correct proportion of powder-to-liquid mix. It could also cause a sterility loss. Avoid resterilization as it may cause infection risks for the patient and cross-contamination with non-sterile objects. Allergic reaction is possible in patients who have a history of allergy to the drug.

Consult

For Use

Do Not Resterilize

Do Not Use If

Resterilization may change and affect the product’s performance, including the effectiveness of the antibiotic. Consult your supplier if you have any questions.

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AB Bone Cement is a single, high-viscosity, radiopaque bone cement containing and its components, including gentamicin sulphate. If the patient has a history of hypersensitivity or serious toxic reactions to aminoglycosides, the use of any other aminoglycosides may also compromise in the affected limb would render the surgical procedure unjustifiable.

For Internal Use Only

AB Bone Cement is contraindicated in the presence of active or incompletely treated infection, at the site where the bone cement is to be applied. Surgeons must be aware of these effects and be prepared to treat the presence of barium sulphate enables radiopacity.

Micronized barium sulphate is not used in the United States due to concerns about its potential complications in patients with chronic or intermittent bowel obstructions. It is not used in open procedures. Barium-containing cements are not recommended for use in patients with bowel obstructions due to the risk of bowel perforation.

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Gentamicin sulphate is an aminoglycoside antibiotic derived from the actinomycete, Streptomyces fradiae. It is a complex of various gentamicins. It is available in different formulations, including an injection and a topical form.

It is given by injection into the bloodstream or muscles and is used to treat bacterial infections that have spread throughout the body (septicemia), serious skin and skin structure infections, sa...