PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

PROPRIETARY NAME (and dosage form)

GARACOLL® 130 mg IMPLANT

GARACOLL® 32,5 mg IMPLANT

COMPOSITION

GARACOLL® 130 mg IMPLANT is available in two sizes which measure 10 x 10 x 0.5 cm and 5 x 20 x 0.5 cm and contains gentamicinsulphate equivalent to 130 mg gentamicin and 280 mg purified bovine collagen.

GARACOLL® 32,5 mg IMPLANT measures 5 x 5 x 0.5 cm and contains gentamicin sulphate equivalent to 32,5 mg gentamicin and 70 mg purified bovine collagen.

PHARMACOLOGICAL CLASSIFICATION

A 14.2 Preparations for the treatment of wounds: Wound dressings

PHARMACOLOGICAL ACTION

GARACOLL Implant is a sterile implant containing gentamicin sulphate, a broad-spectrum antibiotic, and purified collagen from bovine tendons as a carrier substance.

The implant provides locally high concentrations of gentamicin at the site of implantation, resulting in the elimination or prevention of local infection. The implant is completely resorbed.

Gentamicin is an aminoglycoside antibiotic with bactericidal activity. It inhibits normal protein synthesis in susceptible microorganisms. It is active primarily against aerobic gram-negative bacteria. Some activity against gram-positive bacteria has been shown.
In vitro sensitivity against the following organisms has been shown:

Staphylococcus aureus; Staphylococcus epidermidis; Escherichia coli, Proteus mirabilis; Pseudomonas aeroginosa; Klebsiella pneumoniae; Citrobacter freundii; Enterobacter species; Serratia spp*; Providencia stuartii; Salmonella* spp.

The following bacteria are usually resistant to aminoglycosides: *Streptococcus* spp; and most anaerobic organisms such as *Clostridium* spp. and *Bacteroides* spp.

Pharmacokinetics:

A clear relationship between dose and serum or exudate concentration of gentamicin could not be established. It has been postulated that these concentrations are dependent on the local tissue perfusion rate immediately surrounding the tissue site and placement of the implant in the cavity. The exudate levels are always very high on the first days after implantation (2-4 days) and exceed the MIC several times (typically 4 mcg/ml). The maximum serum concentration of gentamicin does not reach toxic levels, and levels of around 3 mcg/ml can be expected in the case of bone infections. In the treatment of soft tissue infections, the peak serum concentrations are found to be higher, generally 4-5 mcg/ml. Serum concentrations did not appear to be dose dependent.

PROFESSIONAL INFORMATION

INDICATIONS

GARACOLL Implant is indicated as adjunctive therapy in the prevention of infection in bone surgery caused by susceptible bacteria. GARACOLL Implant also may be useful for prevention of local infections in bone (such as at the sites of bone grafts or in cementless artificial joint implant).
GARACOLL Implant should not be used as single therapy if infection is present or suspected. Based on microbiologic studies, appropriate systemic antibiotics should be administered concomitantly.

CONTRA-INDICATIONS

Known or suspected hypersensitivity to any of the components or to other aminoglycosides. Patients with a history of immunologic or connective tissue disease.
Safety in pregnancy and lactation has not been established.
Safety of GARACOLL Implant for use in paediatric patients has not been established.

DOSAGE AND DIRECTIONS FOR USE

After surgical debridement of the infection focus, GARACOLL Implant is introduced into the wound cavity. GARACOLL Implant can be cut to the desired size easily with ordinary surgical scissors. It is easier to handle with dry gloves or instruments as it becomes sticky when wet. It can be applied in a variety of ways, including: applied flat as a linear; rolled or folded and packed loosely in a wound cavity; wrapped around the wound site; or cut into small pieces and mixed with macerated cancellous bone for implantation in a bone cavity. GARACOLL Implant is used during surgical procedure and is not removed thereafter.

The dose to be used is dependent on the extent of the operative site and the defect to be treated.

Usually one large implant and up to a maximum of five implants. For smaller defects a large implant can be cut into smaller pieces or a small implant can be used.
(Note that one large implant is equivalent to four small implants.)

Instructions for use

The inner sachet must be removed aseptically from the outer peelable sachet and then the implant removed aseptically from the peelable inner sachet and used dry. Once the outer sachet is opened, the implant must be used or discarded. The product cannot be re-sterilized.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

As low gentamicin serum concentrations are observed, side-effects such as nephrotoxicity and neurotoxicity occur less frequently. The presence of casts, cells or protein in the urine or by rising blood urea nitrogen (BUN), serum creatinine and oliguria could indicate nephrotoxicity. As these side-effects occur more frequently in patients with renal impairment, caution is required in these patients.

Neurotoxicity: Adverse effects on both vestibular and auditory branches of the eighth cranial nerve have been reported, primarily in patients with renal impairment with systemic aminoglycoside administration. Symptoms include dizziness, vertigo, tinnitus, roaring in the ears and hearing loss. The occurrence of vestibular abnormalities may be irreversible.

Local redness, itching and an increase of wound secretion may be observed due to resorption of collagen.
Hypersensitivity reactions to GARACOLL Implant may occur.

Precautions

Although low gentamicin serum concentrations are generally observed with GARACOLL Implant, in patients with a severe renal impairment the benefit of the treatment should be considered carefully. During treatment with GARACOLL Implant alone or concomitantly with systemic aminoglycosides, serum aminoglycoside levels may be measured when feasible and renal function monitored by measurement of serum creatinine levels.

Aminoglycosides should be used with caution in patients with neuromuscular disorders, such as myasthenia gravis and parkinsonism or in infant botulism, since these agents may aggravate muscle weakness because of their potential curare-like effects on the neuromuscular junction.

If several implants are used, insertion of an overflow drain is advisable.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See “Side-Effects and Special Precautions”.

In case of severe overdose, haemodialysis can reduce the serum concentration of gentamicin. Treatment is symptomatic and supportive.

IDENTIFICATION

Opaque white to pale yellow implant with approximate dimensions of 10 x 10 x 0.5 cm, 5 x 20 x 0.5 cm or 5 x 5 x 0.5 cm, free from foreign matter.

PRESENTATION

GARACOLL Implant is double wrapped in peelable sachets contained within an outer carton.

STORAGE INSTRUCTIONS

Store below 25 °C.

Keep out of reach of children.

SHELF LIFE

48 MONTHS

REGISTRATION NUMBER

GARACOLL 130 mg Implant:
34/14.2/0376

GARACOLL 32,5mg Implant:
34/14.2/0375

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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UNDER LICENSE FROM

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