For the use of Registered Veterinary Practitioner or a Hospital or a Laboratory only

BIO-AM

(Amoxycillin & Sulbactam for Injection)

COMPOSITION

Each combi pack contains:

(a) 1 vial of Amoxycillin & Sulbactam for Injection

Each vial contains:

Amoxycillin Sodium IP (Sterile)

eq. to Anhydrous Amoxycillin- 3g

Sulbactam Sodium IP (Sterile)

eq. to Anhydrous Sulbactam-1.5g

(b) 1 Ampoule of Sterile Water for Injections IP

Each FFS Ampoule contains: 20ml

Sterile Water for Injections IP

Vital information on Amoxycillin + Sulbactam combination

Resistance to many antibiotics is caused by bacterial enzymes such as B-lactamase, which destroy the antibiotic before it can act on the pathogens. The Sulbactam Sodium in 'BIO-AM' anticipates this defence mechanism by blocking the B-lactamase enzymes, thus rendering the organism's sensitive to Amoxycillin Sodium's rapid bactericidal effect at concentrations readily attainable in the body. Sulbactam by itself has little antibacterial activity; however, in association with Amoxycillin as 'BIO-AM', it produces an antibiotic agent of broad-spectrum activity with wide applications. The pharmacokinetics of the two components of 'BIO-AM' is closely matched. Both Sulbactam and Amoxycillin Sodium have low levels of serum binding; about 70% remain free in the serum. Doubling the dosage of '"BIO-AM' approximately doubles the serum levels achieved.

CLINICAL INFORMATION:

'BIO-AM' is a formulation of Amoxycillin Sodium, a bactericidal broad-spectrum Penicillin and Sulbactam Sodium, a progressive and irreversible inhibitor of beta-lactamase enzymes. The presence of Sulbactam Sodium protects Amoxycillin Sodium from destruction and subsequent loss of antibacterial activity by the B-lactamase enzymes produced by many Gram-ve and Gram +ve bacteria. The spectrum of Amoxycillin is thus widened to include organisms, normally by virtue of their ability to produce Beta- lactamase. Amoxycillin 'will not only eliminate primary pathogens but also not get inactivated by non-pathogenic beta-lactamase producing organisms at the site of infection.

INDICATIONS:

As a safe, broad-spectrum penicillin, Amoxycillin has been found of value in a wide variety of bacterial infections in animals. In farm animals infections treated include those of respiratory, alimentary, Genito-urinary, skin and soft tissue and mammary glands.

In dogs and cats, the indications include respiratory infections, skin and soft tissue infections, enteric infections and infections of Genito-urinary tract. 'BIO-AM' is indicated for the treatment of common bacterial infections where antibiotic therapy is indicated, including.

Upper Respiratory Tract Infections: e.g. Sinusitis, Tonsilitis, Otitis media, Lower Respiratory Tract Infections, Acute and chronic bronchitis and Bronchopneumonia.

Genito-urinary Infections: e.g. Cystitis, Urethritis, Pyelonephritis, Female genital infections like Metritis, Endometritis, Cervicitis & Pyometra.

Skin and Soft Tissue Infections: e.g. Mastitis, Abscesses, Cellulitis, Wound infections.

Bone and Joint Infections: e.g. Osteomyelitis.

Other Infections: e.g. Septicemia, Peritonitis, Post-operative infections, Intra-Abdominal sepsis, Septic abortion,

BACTERIOLOGY

'BIO-AM 'is bactericidal to a wide range of Gram+ve and Gram-ve bacteria including many clinically important beta-lactamase producing penicillin resistant organisms, like:

Gram Positive:

Staphylococcus aureus,
Streptococcus agalactiae
Corynebacterium pyogenes
Coagulase-negative
Streptococcus pyogenes
Enterococcus faecalis
Listeria monocytogenes
Streptococcus spp.
Staphylococcus aureus (ß Lactamase + ve)
Streptococcus dysgalactiae
Clostridium spp.
Streptococcus pneumoniae
Staphylococcus epidermidis
Bacillius anthracis
Streptococcus viridans

Gram Negative:

Escherichia coli
Klebsiella spp.
Pseudomonas aeruginosa
Bordetella bronchiseptica
Bacteroides spp.
Mycoplasma
Brucella spp. *(Lactamase + ve)*
Salmonella spp.
Haemophilus spp.
Pasteurella spp.
Treponema hyodysenteriae

DOSAGE:

Large Animals Usually 3000 mg - 4500 mg. 24 hourly by IV or IM Route.
In more serious infections, increase frequency-12 hourly intervals.
Treatment with BIO-AM' should not extend beyond 14 days without review. Dosage for surgical prophylaxis: Surgical prophylaxis with 'BIO-AM' should aim to protect the patient for the period of risk of infection. Accordingly, procedures lasting for less than 1 hour are covered in large animals by 3000 mg 4500 mg. BIO-AM' given at induction of anaesthesia. Longer operations require subsequent doses of 3000 mg - 4500 mg. 'BIO-AM' (up to 4 doses in 24 hours), and this regime can be continued for several days if the procedure has significantly increased the risk of infection. Clear clinical signs of infection at operation will require a normal course of 'BIO-AM' therapy post-operatively.

PREPARATION AND ADMINISTRATION:

4500 mg vial: Constitute with requisite quantity from the Sterile Water for Injections IP 20 ml provided with this pack. The constituted solution should be used immediately after preparation. 3000 mg vial: Constitute with requisite quantity from the Sterile Water for Injections IP 10 ml provided with this pack. The constituted solution should be used immediately after preparation.
IV, IM Injection BIO-AM may be administered either by intravenous, intramuscular or by intramammary route.

STABILITY AND COMPATIBILITY

The stability of 'BIO-AM’ solution is concentration dependent, thus 'BIO-AM’ should be used immediately upon reconstitution and given by slow intravenous injection over a period of 3-4 minutes or can be given by intramuscular route. 'BIO-AM’ solution should be used within 20 minutes of reconstitution. 'BIO-AM’ may be injected directly into a vein or via a drip tube. Intravenous infusions of 'BIO-AM’ may be given in a range of different intravenous fluids. 'BIO-AM’ should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions. If 'BIO-AM’ is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or

giving set because loss of the aminoglycoside can occur under these conditions.

CONTRA-INDICATIONS, WARNINGS, ETC.
Safety of Amoxycillin is typical of that of other penicillins, in that intrinsic toxicity is very low, except in animals with specific allergy to beta lactams and this seems rare in animals. Diarrhoea as a side effect is uncommon in animals.

PRECAUTIONS
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in animals with a history of penicillin hypersensitivity. Erythematous rashes have been associated with glandular fever in patients receiving Amoxycillin Sodium. During the administration of high doses of 'BIO-AM' adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria. When present at high concentration in urine at room temperature, Amoxycillin Sodium may precipitate in bladder catheters.

INTERACTIONS
'BIO-AM' should be used with care in patients on anticoagulation therapy.

USE IN PREGNANCY AND LACTATION
Reproduction studies in animals (mice and rats) with orally and parenterally administered 'Amoxycillin' have shown no teratogenic effect 'BIO-AM' may be administered during the period of lactation.

OVERDOSAGE
Problems of overdosage with 'TOXOMOX SB' are unlikely to occur.

STORAGE
Store in a dry place at a temperature not exceeding 30C. Protect from light. Do not allow to freeze.
Keep out of reach of children.
Do not use if constituted solution is not clear or has suspended matter.

WITHDRAWAL PERIOD
Meat : 28 days after the last administration.
Milk : 7 days after the last administration.

PRESENTATION
Available in 3g & 4.5g vial.

For IM/IV & Intramammary use
(Combi pack with Sterile Water for Injections IP)

VETERINARY. NOT FOR HUMAN USE

FOR ANIMAL TREATMENT ONLY

Carefully read the accompanying instructions before use.

SAVAVET
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