

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

TOXO-MOX SB

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(Amoxycillin & Sulbactam for Injection 375 mg / 750 mg)

COMPOSITION:

TOXO-MOX SB 375

Each vial contains:

Amoxycillin Sodium (Sterile) IP
Eq. to Amoxycillin 250mg
Sulbactam Sodium (Sterile) USP
Eq. to Sulbactam 125mg

TOXO-MOX SB 750

Each vial contains:

Amoxycillin Sodium (Sterile) IP
Eq. to Amoxycillin 500mg
Sulbactam Sodium (Sterile) USP
Eq. to Sulbactam 250mg

DESCRIPTION

TOXO-MOX SB (Amoxycillin Sodium IP & Sulbactam Sodium USP) is the broad-spectrum antibiotic Amoxycillin Sodium and the β -lactamase inhibitor, Sulbactam (Sulbactam sodium salt of Sulbactam)

Amoxycillin Sodium is a semisynthetic antibiotic with a broad spectrum of bactericidal activity against many gram-positive and gram-negative, aerobic and anaerobic microorganisms. It does not resist destruction by β -lactamases; therefore, it is not effective against β -lactamase producing bacteria. Chemically, it is D(-)- α -amino-p-hydroxybenzyl penicillin Sodium.

Sulbactam, an inhibitor of β -lactamase enzymes, is produced by the fermentation of *Streptomyces clavuligerus*. Sulbactam by itself has only weak antibacterial activity.

CLINICAL PHARMACOLOGY

Amoxycillin is bactericidal in action and acts through the inhibition of biosynthesis of cell wall mucopeptide of susceptible organisms. The action of Sulbactam extends the antimicrobial spectrum of Amoxycillin to include organisms resistant to Amoxycillin and other β -lactam antibiotics.

The components are rapidly absorbed resulting in Amoxycillin and Sulbactam concentrations in serum, urine, and tissues similar to those produced when each is administered alone.

Amoxycillin and Sulbactam diffuse readily into most body tissues and fluids with the exception of brain and spinal fluid, which Amoxycillin penetrates adequately when meninges are inflamed. Most of the Amoxycillin is excreted unchanged in the urine. Sulbactam's penetration into spinal fluid is unknown at this time. Approximately 15% of the administered dose of Sulbactam is excreted in the urine by kidney.

TOXO-MOX SB combines the distinctive properties of a broad-spectrum antibiotic and a β -lactamase inhibitor to effectively extend the antibacterial spectrum of Amoxycillin to include β -lactamase producing as well as non- β -lactamase producing aerobic and anaerobic organisms.

MICROBIOLOGY

Amoxycillin/sulbactam has been shown to have a wide range of activity which includes β -lactamase producing strains of both gram-positive and gram-negative aerobes, facultative anaerobes, and obligate anaerobes. Many strains of the following organisms, including β -lactamase producing strains, isolated from veterinary sources, were found to be susceptible to Amoxycillin/Sulbactam in vitro but the clinical significance of this activity has not been demonstrated for some of these organisms in animals.

Aerobic bacteria, including *Staphylococcus aureus*, β -lactamase producing *Staphylococcus aureus* (penicillin resistant), *Staphylococcus species*, *Staphylococcus epidermidis*, *Staphylococcus intermedius*, *Streptococcus faecalis*, *Streptococcus species*, *Corynebacterium pyogenes*, *Corynebacterium species*, *Erysipelothrix rhusiopathiae*, *Bordetella bronchiseptica*, *Escherichia coli*, *Proteus mirabilis*, *Proteus species*, *Enterobacter species*, *Klebsiella pneumoniae*, *Salmonella dublin*, *Salmonella typhimurium*, *Pasteurella multocida*, *Pasteurella haemolytica*, *Pasteurella species*. Studies have demonstrated those both aerobic and anaerobic floras are isolated from gingival cultures of dogs with clinical evidence of periodontal disease. Both gram-positive and gram-negative aerobic and anaerobic subgingival isolates indicate sensitivity to Amoxycillin/Sulbactam during antimicrobial susceptibility testing.

INDICATIONS AND USAGE

TOXO-MOX SB Injection is indicated in the treatment of:

Dogs

Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β -lactamase producing *Staphylococcus*

aureus, non- β -lactamase producing *Staphylococcus aureus*, *Staphylococcus spp.*, *Streptococcus spp.*, and *E. coli*.

Periodontal infections due to susceptible strains of aerobic and anaerobic bacteria. TOXO-MOX SB has been shown to be clinically effective for treating cases of canine periodontal disease.

Cats

Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: β -lactamase producing *Staphylococcus aureus*, non- β -lactamase producing *Staphylococcus aureus*, *Staphylococcus spp.*, *Streptococcus spp.*, *E. coli*, *Pasteurella multocida*, and *Pasteurella spp.*

Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Therapy may be initiated with TOXO-MOX SB prior to obtaining results from bacteriological and susceptibility studies.

DOSAGE AND ADMINISTRATION

Dogs and Cats:

10 mg of amoxycillin per kg body weight at every 12 hours interval or as directed by Veterinarian

Reconstitution Instructions - Injection

Dissolve the contents of vial using sterile water for injection IP. The constituted solution should be used immediately after preparation.

CONTRAINDICATIONS

The use of this drug is contraindicated in animals with a history of an allergic reaction to any of the penicillin or cephalosporins.

WARNINGS

Safety of use in pregnant or breeding animals has not been determined.

For use in dogs and cats only

NOT FOR HUMAN USE

FOR ANIMAL TREATMENT ONLY

ADVERSE DRUG REACTIONS

TOXO-MOX SB contains semisynthetic penicillin (Amoxycillin) and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

STORAGE

Store below 25°C. Protect from light.

Keep out of reach of children.

PRESENTATION: Glass vial with 10 ml water for Injections IP.

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