For the use of Registered Veterinary Practitioner, Hospital or Laboratory

TOXO-MOX

(Amoxycillin and Potassium Clavulanate Tablets and Oral Suspension IP)

Composition:

Each film coated tablet of **TOXO-MOX 250mg** contains:

Amoxicillin Trihydrate I.P	
Eq. to Amoxicillin	200 mg
Potassium Clavulanate I.P	
Eq. to Clavulanic Acid	50 Mg
Excipients Q.S	

Each film coated tablet of **TOXO-MOX 500mg** Contains:

Amoxicillin Trihydrate I.P	
Eq. to Amoxicillin	400 mg
Potassium Clavulanate I.P	
Eq. to Clavulanic Acid	100 mg
Excipients Q.S	

Each 5 ml reconstituted of **TOXO-MOS Oral Suspension** contains:

Amoxycillin Trihydrate IP	
Eq. to Amoxycillin	200 mg
Potassium Clavulanate Diluted IP	
Eq. to Clavulanic Acid	28.5 mg
Excipients	q.s.

Description:

TOXO-MOX (Amoxycillin trihydrate and Potassium clavulanate as Tablets and Oral Suspension) is an orally administered formulation comprised of the broad-spectrum antibiotic Amoxycillin trihydrate and the β-lactamase inhibitor, Potassium clavulanate (the potassium salt of clavulanic acid).

Amoxycillin trihydrate 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 trihydrate.

Clavulanic acid, an inhibitor of β-lactamase enzymes, is produced by the fermentation of Streptomyces clavuligerus. Clavulanic acid by itself has only weak antibacterial activity. Chemically, Clavulanate potassium is potassium z-(3R,5R)-2-β-hydroxyethylidene clavam-3-carboxylate.

Clinical Pharmacology:

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

TOXO-MOX is stable in the presence of gastric acid and is not significantly influenced by gastric or intestinal contents. The components are rapidly absorbed resulting in amoxycillin and clavulanic acid concentrations in serum, urine, and tissues similar to those produced when each is administered alone. Amoxycillin and clavulanic acid 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. Clavulanic acid's penetration into spinal fluid is unknown at this time. Approximately 15% of the administered dose of clavulanic acid is excreted in the urine within the first 6 hours.

TOXO-MOX 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/Clavulanate 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/Clavulanate 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/Clavulanic acid during antimicrobial susceptibility testing.

Indications and Usage:
TOXO-MOX 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 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.

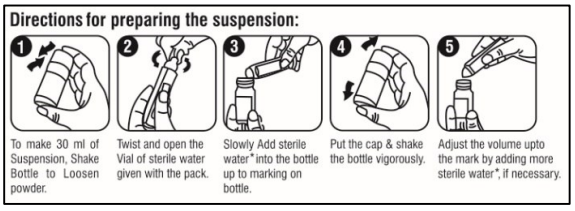
Therapy may be initiated with TOXO-MOX Dry Syrup prior to obtaining results from bacteriological and susceptibility studies.
A culture should be obtained prior to treatment to determine susceptibility of the organisms to TOXO-MOX Dry Syrup. Following determination of susceptibility results and clinical response to medication, therapy may be reevaluated.

Dosage and administration:
Dogs and Cats: The recommended dosage is 12.5 mg/kg of body weight twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5–7 days or for 48 hours after all symptoms have subsided.

While using TOXO-MOX oral suspension,
- In skin and soft tissue infections, the dosage is 1ml/3kg bw b.i.d.
- In periodontal infections, the dosage is 1ml/3kg bw (5 – 7 days)
- In Deep pyoderma, the dosage is 1ml/3kg bw (21 – 30 days)

If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

Reconstitution Instructions:
Oral Suspension
Slowly add sterile water up to the ring mark on the bottle. Shake vigorously. Adjust the volume upto the ring mark by adding more water, if necessary. This makes 30 ml suspension. Use the reconstituted suspension within 4 days after reconstitution. Each mL of suspension will contain 40 mg of amoxycillin activity as the trihydrate and 5.7 mg of clavulanic acid activity as the potassium salt.



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

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

VETERINARY
FOR USE IN DOGS AND CATS ONLY
NOT FOR HUMAN USE
FOR ANIMAL TREATMENT ONLY

Adverse Drug Reactions:
TOXO-MOX contains semisynthetic penicillin (amoxycillin) and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

Presentation:
TOXO-MOX tablets are available as a strip of 10 tablets

TOXO-MOX Oral Suspension is available as 30ml Bottle with Sterile Water.
Store below 25°C, protected from light & moisture.
Refrigeration of the reconstituted suspension is required.

Keep out of reach of children.
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