

OSMOXYL-50S WATER SOLUBLE POWDER

Composition

Each g contains:

Amoxicillin Trihydrate500mg

Product Description

Osmoxyl-50S Water Soluble Powder is an off white powder

Pharmacodynamics

Amoxicillin is a bacterial antibiotic belonging to the group of semisynthetic penicilins with a broad spectrum of activity against Gram positive and Gram negative bacteria. It owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

Pharmacokinetics

Amoxicillin is well absorbed following oral administration and it is stable in the presence of gastrics acids. Excretion of amoxicillin is mainly in the unchanged form via the kidneys to give high concentration in renal tissue and urine.

Amoxicillin is well distributed in body fluids.

Indication

Chickens: Treatment of infections in chickens caused by bacteria susceptible to amoxicillin.

Pigs: For the treatment of pasteurellosis.

Mode of Administration

Orally via drinking water

Recommended Dosage

In drinking water use.

Chickens: The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 30 mg product/kg bodyweight/day).

The total period of treatment should be for 3 days or in severe cases for 5 days.

Pigs: Administer in the drinking water to give 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 40 mg product/kg bodyweight) daily for up to 5 days.

Contraindications

This product should not be administered to rabbits, guinea pigs, hamsters, gerbils or any other small herbivore.

Do not use in animals with known hypersensitivity to penicillins or other β -lactam antibiotics or to any of the excipients.

Do not administer to animals with renal disease including anuria or oliguria.

Warnings and Precautions

Special warnings for each target species

None.

Special warnings for use

Special precautions for use in animals

Not effective against beta-lactamase producing organisms.

Pigs: The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animals. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity to the active substance or if you have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143

Wear gloves during preparation and administration of medicated water or liquid feed

Wash any exposed skin after handling the product or medicated water or feed

Wash hands after use

Interactions with Other Medicaments

The product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides.

Pregnancy and Lactation

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to administration of amoxicillin.

Use only according to the benefit/risk assessment of the responsible veterinarian.

Do not use in birds producing eggs for human consumption or within 3 weeks of onset of laying.

Adverse Effects/Undesirable Effects

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

Overdose and Treatment

No problems with overdosage have been reported. Treatment should be symptomatic and no specific antidote is available.

Withdrawal Period(s)

Meat and offal:

Chickens: 1 day

Pigs: 2 days

Not authorized for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

Storage condition

Store in a cool dry place, protected from sunlight. Do not store above 30°C.
Keep out of reach of children/Jauhkan dari kanak-kanak.

Pack size(s)

Aluminium sachet of 100g and 500g

Product Registration Holder/ Manufacturer

Osmosis Nutrition Sdn. Bhd. (594876A)
Lot 16014(P.T. 24341), Jalan Nilam 3,
Bandar Nilai Utama,
71800 Nilai, Negeri Sembilan, Malaysia.
Tel: +606-799 9090 Fax:+606-799 9155

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