

D4. Product Information Leaflet

i) Name of Product

AMOX FORTE Water Soluble Powder 500 mg/g

ii) Description of Product

An oral water soluble powder containing Amoxicillin trihydrate

iii) What is the medicine?

AMOX FORTE Water Soluble Powder 500 mg/g containing antibiotic Amoxicillin trihydrate to treat infections in Chickens, turkeys, ducks, and Pigs

iv) Strength of the medicine

Amoxicillin trihydrate 500 mg/g

v) What is this medicine used for?

The medicine used for :

- Chickens, turkeys and ducks : Treatment of infections caused by bacteria susceptible to amoxicillin
- Pigs : For the treatment of pasteurellosis caused by *Pasteurella multocida* susceptible to amoxicillin

vi) How much and how often should you give this medicine to animal?

Species	Recommended dose
Chickens	The recommended dosage is 15 mg amoxicillin trihydrate per kg body weight per day (corresponding to 30 mg product/kg body weight/day). The total period of treatment should be for 3 days or in severe cases for 5 days
Ducks	The recommended dosage is 20 mg amoxicillin trihydrate per kg body weight per day (corresponding to 40 mg product/kg body weight/day) for 3 consecutive days
Turkey	The recommended dosage is 15-20 mg amoxicillin trihydrate per kg body weight per day (corresponding to 30 - 40 mg product/kg body weight/day) for 3 days or in severe cases for 5 days
Pigs	For the medication of pigs, the product may be administered via the drinking water. It may not be used in dry feeds. Administer in the drinking water to give 20 mg amoxicillin trihydrate per kg body weight (corresponding to 40 mg product/kg body weight/day) daily for up to 5 days. Prepare the solution by carefully mixing the product in the requisite quantity of fresh potable water immediately before use. The dose should be administered at approximately 24 hourly intervals for up to 5 days. Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished. In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being on treatment

vii) When should you not give this medicine to animal?

- Do not administer to rabbits, guinea pigs, hamsters, horses, gerbils or any other small herbivore
- Do not use in animals with known hypersensitivity to penicillins or other β -lactam antibiotics or to the excipient
- Do not administer to animals with renal disease including anuria or oliguria

viii) Undesirable effects/ side effects

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious. Rarely, gastrointestinal tract signs associated with alteration of the intestinal flora (for example, loose stools, diarrhea) may occur

ix) What other medicine or food should be avoided whilst giving this medicine to animal?

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

x) What should you do if you miss a dose for the animal?

Consult to your veterinarian when you miss a dose. You may get advise to prolong the course of treatment or add an additional, more powerful antibiotic to fully combat the infection.

xi) How should you keep this medicine?

Store at temperature below 30°C in a tightly closed container, in a dry and cool place, protected from direct sunlight

xii) Signs & symptoms of overdose

No overdose problems have been reported

xiii) What to do when you have given more than the recommended dosage to the animal?

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

xiv) Name/logo of manufacturer/importer/marketing authorisation holder

PT Medion Farma Jaya

Jl Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat – Indonesia

xv) Care that should be taken when giving this medicine to animal?

Special precautions for use in animals

- Not effective against beta-lactamase producing organisms
- 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 animal. 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

- Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations
- 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

xvi) When should you consult your veterinarian?

When there is no improvement in animal health after administration according to the recommended dose, when the appearance of toxic symptoms or in case of insufficient water uptake, animals should be treated parenterally instead using a suitable injectable product prescribed by the veterinarian.