

Amovet 50%

(Amoxicillin) POWDER

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اکھوگرام

1kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT AMOVET 50% POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains: Amoxicillin (As trihydrate) 500 mg

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. CLINICAL DATA

4.1 Species of animals for which the VMP is intended

Chickens

4.2 Indications

Amovet 50% powder is a versatile antibiotic used in poultry to treat respiratory infections like chronic respiratory disease (CRD) and colibacillosis, as well as gastrointestinal infections such as bacterial enteritis. It is effective against a wide range of gram-positive and gram-negative bacteria, making it essential for managing septicemia and other systemic infections. Additionally, Amoxicillin is often used preventively in at-risk flocks and to prevent secondary bacterial infections during viral outbreaks, helping to maintain the overall health and productivity of the flock.

4.3 Contraindications

Do not use in rabbits, hamsters, gerbils or birds that produce or are intended to produce eggs for human consumption.

4.4 Special precautions for each type of animal for which the VMP is intended

There is no.

4.5 Special precautions for use

Special precautions for animals when using the product Chicken: intake of animal products may be Special precautions for persons administering the veterinary medicinal product to animals

Penicillins and cephalosporins can cause hypersensitivity (allergy) after injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins can lead to cross-reactions with cephalosporins and vice versa. Allergic reactions to these substances can sometimes be serious.

1) Do not work with this product if you know you are sensitive or if you have been advised not to work with such products.

2) Handle this product carefully to avoid exposure, observing all recommended precautions.

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

• Avoid breathing dust. Personal protective equipment consisting of a single-use disposable mask respirator conforming to European standard EN149 or a single-use respirator conforming to European standard EN140 with filter according to EN143, must be worn when working with the veterinary medicinal product.

• Wear gloves during the preparation and application of medicated water or food.

• Wash any exposed skin surface after using the product or medicated water or food.

• Wash hands after use.

4.6 Adverse reactions (frequency and importance)

Not known.

4.7 Use during pregnancy, lactation or ovulation

Laboratory studies in rats showed no evidence of teratogenicity due to the administration of amoxicillin.

It is only applied after a benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other veterinary medicinal products and other forms of interaction

Not known.

4.9 Dosage and method of administration

Chickens

The product is applied in drinking water. Prepare the solution with fresh tap water immediately before use. After opening, use the contents of the package immediately. Any unused medicated water should be discarded after 12 hours. To ensure consumption of the medicated water, the animals must not have access to other water sources during treatment.

1gm powder in 3 Litter /Use 3 to 5 days.

The following formula can be used to calculate the required amount of the product per day (in g):

Number of birds x average body weight (kg) 25 (for 20 mg/kg) or 33 (for 15 mg/kg)

To ensure that the correct dose is taken, body mass should be determined as accurately as possible to avoid administration of a lower dose. The intake of medicated water depends on the clinical condition of the birds. To obtain the correct dosage, the concentration of amoxicillin should be adjusted taking into account water intake.

Chickens:

The recommended dose is 15 mg amoxicillin as trihydrate per kg body weight. The total treatment period should be 3 days or in more severe cases 5 days.

Application in drinking water

Administer in drinking water to provide 20 mg/kg body weight, daily. The dose should be divided and administered at approximately 12 hourly intervals for up to 5 days. Dissolve in the required amount of water immediately before use.

For use in drinking water, the solution must be prepared with fresh drinking water.

• Any medicated water that is not consumed within 12 hours must be thrown away

• To ensure consumption of medicated water, animals should not have access to other water sources during treatment.

Application with liquid feed

Administer in liquid feed to provide 20 mg amoxicillin trihydrate/kg body weight daily for up to 5 days. The medicated food must be freshly prepared, at least 3 times a day during the treatment period. The daily dose should be calculated based on the number of animals and the average body weight and then divided by the number of feed batches prepared during the day. ÿ Liquid medicated food should be prepared with fresh drinking water.

Dissolve the required amount of the product in water at a concentration of 25 g/L before adding to the feed. ÿ After adding the product to some or all of the water required to prepare the liquid feed, ensure that the product is completely dissolved. The product may take up to 10 minutes to dissolve. This medicated water can then be mixed with dry complete feed and, if appropriate, the remaining water. The system used must ensure that the medicated water is evenly distributed in the food. Medicated food should not be stored.

The stability of amoxicillin has not been proven in all commercial feeds. To ensure that any loss of amoxicillin activity is minimized, the amount of medicated feed prepared should not exceed the amount of feed that will be consumed within 4 hours.

- Any medicated food that is not consumed within 4 hours should be thrown away
- Although limited access to other water sources would facilitate the consumption of medicated food, separate clean drinking water should remain available

availability at any time for reasons related to good health of animals.

4.10 Overdose (symptoms, emergency measures, antidotes), if necessary

No cases of overdose have been reported. In case of overdose, the treatment should be symptomatic, as there is no specific antidote.

4.11 Withdrawal Period

Meat and Offal:
Chickens: 1 day.

Not authorized for use in birds producing or intended to produce eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amoxicillin is a bacterial semi-synthetic penicillin with a broad spectrum of action against Gram-positive and Gram-negative microorganisms. It owes its activity to the inhibition of the development of the structure of the peptidoglycan network in the bacterial one cell wall.

5.2 Pharmacokinetic features

Amoxicillin is well absorbed after oral administration and is stable in the presence of gastric acids. Excretion of amoxicillin is mainly in unchanged form through the kidneys, due to the high concentration in the kidney tissue and urine. Amoxicillin is well distributed in body fluids.

Studies in birds have shown that amoxicillin is distributed and eliminated more rapidly than in mammals. Biotransformation appears to be a more important route of elimination in birds than in mammals.

6. PHARMACEUTICAL PROPERTIES

6.2 Major Incompatibilities

Not known.

6.3 Expiry Date

Shelf life of the final veterinary medicinal product: 2 years. Shelf life after first opening the primary packaging: 30 days.

Shelf life after reconstitution or dilution according to instructions: 12 hours. Shelf life after mixing with liquid feed: 4 hours.

6.4. Special conditions for product storage

- Store below 30°C in a dry place.
- Protect from light & Moisture.
- Keep out of reach of children.

6.5 How supplied

1kg Jar.