

## **Consumer Leaflet for a Veterinary Product**

This medicine is marketed according to a veterinarian's prescription only.  
For animal use only

### **1. Name of the veterinary medicine, form and strength**

Ampivet Veterinary, Powder for solution, Per os in drinking water

### **2. Active ingredients and quantity in a single dose:**

Ampicillin (as sodium) 75 g /100 g

1 g contains 750 mg Ampicillin (equivalent to ampicillin sodium 800 mg)

For the full list of excipients- see section 13 "Additional information" in this leaflet.

### **3. What is the medicine intended for**

For infections of broilers due to Gram-positive and Gram-negative microorganisms sensitive to ampicillin.

**Therapeutic group:** penicillins, beta-lactam antibiotics.

### **4. Contra-indications**

Do not use in animals with known hypersensitivity to the penicillin or to other beta-lactam antibiotics.

Do not use the medicine where cases of resistance to the penicillins are known.

Do not administer to rabbits, guinea-pigs, hamsters, chinchillas or rodents generally.

### **5. Side effects**

In hypersensitive subjects, allergic phenomena may occur, with clinical symptoms varying from transitory skin reactions to anaphylactic shock. Any allergic phenomena can be treated through prompt injection of antihistamines and analeptics (central nervous system stimulants).

Ampicillin has a high therapeutic index with rare undesirable effects, mainly to the gastroenteric system. Use, particularly in mammals and especially if prolonged, of ampicillin, can give rise to damage to intestinal flora with appearance of symptoms such as diarrhoea, nausea and gastralgia.

If severe adverse reactions or other reactions not mentioned in this package leaflet should occur, please inform the treating veterinarian.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site ([www.health.gov.il](http://www.health.gov.il)), which leads to an online form for reporting side effects. Alternatively, you can use the following link:

<https://sideeffects.health.gov.il/>

### **6. Target animals**

Broilers

### **7. Dosage and administration**

Dissolve the product in drinking water in a daily dose of 300-400 gr per 1000 liter (corresponding to 20-30 mg per kg body weight/day of ampicillin).

The treatment will be given twice a day, each time half of the daily dose.

The administration must be renewed every 12 hours, which is the length of time the medicine remains stable in water.

The duration of treatment is 3 to 5 days.

In cases of acute infection, the dose can vary according to the instructions of a veterinarian.

The brimful measuring spoon contains 13.5 g of product, equivalent to 10 g of ampicillin.

## 8. How to use the product

Dissolve the product in drinking water (detailed instructions in section 7).

### Advice on correct administration

- If the product is added to the cistern, it is advisable to block the valve or close off supply of the main conduit.
- For preparation of large masses of medicated water, it is useful to prepare a concentrated solution beforehand, in order to better control the perfect solubilisation of the powder, exactly calculating the quantity of medicinal product required to obtain the right concentration in the final cistern.
- Add the concentrated solution to the cistern containing a quantity of water required for the birds for 12 hours. Fill the cistern every 12 hours for the duration of the treatment.
- Do not add non-medicated water during the treatment period.
- Keep the cistern and drinker cups as clean as possible.
- After use, wash the cisterns and the tubing carefully.

## 9. Withdrawal period

Do not slaughter the Broiler chickens for meat during treatment.

You must wait a period of 3 days before slaughter.

Use not permitted in layer hens producing eggs for human consumption.

## 10. Warnings

### • Special precautions for safety use in animals

- Use of the product should be based on sensitivity testing against the bacteria isolated from the animals to be treated. If this should not be possible, therapy must be based on local (regional, farm) epidemiological information on the sensitivity of the target bacteria. Use of the product other than in the instructions supplied may lead to an increase in the incident of resistant bacteria and reduce the efficacy of treatments with other antibacterial agents, owing to the possible appearance of cross-resistance.
- Do not leave water containing ampicillin available to other animals not being treated or to wild animals.
- Do not mix with solid feeds.

### • Special precautions to be taken by the person administering the medicinal product to animals

People with known hypersensitivity to ampicillin must avoid contact with the product.

Hypersensitivity to the penicillins may be associated with cross-reactivity to the cephalosporins and vice versa.

Wash the hands after use.

To avoid inhalation of the powder and skin contact, use protective mask and gloves. In case of contamination, rinse with plenty of soap and water.

- Use during egg production  
Use not permitted in layer hens producing eggs for human consumptions.
- Interaction with other medicinal products and other forms of interaction  
The bactericidal action of penicillin is neutralized by bacteriostatic agents (macrolides, sulphonamides and tetracyclines).  
Concurrent use with probenecid and sulfinpyrazone produces a reduction in elimination of the penicillins.
- Overdose  
No symptoms due to overdose, linked to use of the product, are known. Do not exceed the recommended doses.
- Incompatibilities  
In the absence of compatibility studies, do not mix with other veterinary medicinal products.

#### **11. Storage instructions**

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions:
  - Store below 25°C in a cool and dry place.
  - The product can be used for 3 months after first opening the container.
  - After dilution in drinking water the product can be used within 24 hours.

#### **12. Instructions for disposing of the product / remaining product at the end of its use**

Any unused veterinary medical product or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

#### **13. Additional information**

- in addition to the active ingredient, this medicine also contains: Anhydrous dextrose
- How does the medicine look like and what is the content of the package:  
White powder
- Pack size: a container of 1340 grams contains 1,072 grams of Ampicillin sodium (equivalent to 1000 grams of Ampicillin), and a measuring spoon.
- Registration holder: Romat Ltd, Ha'maapilim 39/104, Herzliya 46543
- Manufacturer: FATRO S.P.A., VIA EMILIA 285 - 40064, OZZANO EMILIA, BOLOGNA, ITALY

Revised in July 2022 according to Ministry of Health instructions.

Registration number of this medicine in the Ministry of Health State Medicine Registry:  
083-55-92371