Consumer Leaflet for a Veterinary Product

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

For use on animals only

1. Name of the veterinary medicine, form and strength

Supramox S.P. Veterinary

Powder for solution in drinking water

2. **Active ingredient** and its quantity in a single dose

Amoxicillin 700 mg/g (equivalent to amoxicillin trihydrate 800 mg/g)

For a list of the product's inactive ingredients, see paragraph 13, "Additional Information"

3. What is the medicine intended for:

Treatment of infections due to microorganisms sensitive to amoxicillin in broilers.

Pharmaceutical group: penicillin antibiotics.

4. Contraindications

Do not use in cases of hypersensitivity to penicillin or to other beta-lactam products.

Do not use in rabbits and other rodents such as guinea pigs, hamsters or gerbils.

5. Side effects

Possible side effects: hypersensitivity with varying severity, from skin rash to anaphylactic shock. In such cases, stop treatment.

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), which leads to an online form for reporting side effects. Alternatively, you can use the following link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=adversEffectMedic@moh.gov.il

6. Target animals

Broilers

7. Dosage and administration method

10-20 mg Supramox powder per 1 kg of body weight (8-16 mg/kg of amoxicillin trihydrate) daily, for 3-5 days. In serious infections, it is recommended to administer the higher dosage.

Loading (bolus) dose: It is recommended that the product will be given once a day in the animal's drinking water for a limited period of time (see details in the following paragraph).

Use the following formula to calculate the daily quantity of the product:

$$\frac{\text{Average weight of the birds x number of birds}}{50 \text{ (for 20 mg per kg) or } 100 \text{ (for 10 mg per kg)}} = \text{grams of medicine per day}$$

Continuous dosage: Calculate the quantity of the medicine to be administered in accordance with the daily water consumption:
Chickens age 0-4 weeks: 6-12 grams of Supramox powder for 100 liters of water per day.
Chickens age above 4 weeks: 10-20 grams Supramox powder for 100 liters of water per day.

8. How to use the product

Supramox may be administered in drinking water continuously or in Concentrated (bolus) manner.

Concentrated (bolus administration) dose:
Administer once a day in drinking water for a limited period of time. Shut off the regular water supply for about 2 hours (or less in hot weather) before administering. Distribute the daily dosage of the powder over 5-10 liters of water and mix until dissolved. Add the solution to the volume of drinking water usually consumed over 2-3 hours while mixing. After the animals have finished drinking the treatment solution, renew the regular water supply.

Continuous dose:
If continuous administration is preferred, prepare the quantity of treatment solution to be consumed over 12 hours according to the formula in the paragraph "Dosage and administration method." The treatment solution should be renewed every 12 hours (administration twice a day).

In order to ensure an accurate dosage, determine the body weight as accurately as possible. Take into account the animals' drinking patterns, which depend on their clinical condition. Adjust the medicine concentration in the drinking water in order to ensure that the animal receives the entire recommended dosage of the active ingredient. It should be noted that the maximum solubility of the product is 6 grams of the product per 1 liter of water. It is recommended to use a calibrated scale.

During treatment, make sure that the animals do not have access to water that does not contain the medicine.

Enclosed in the package is a measuring spoon that holds 10 gr. of Supramox.

9. Withdrawal period

Broilers – 24 hours

Do not use the medicine in egg-laying chickens or for a period of 4 weeks before the onset of the egg-laying period.

10. Warnings

- Do not use the medicine solution if more than 24 hours have passed since the solution was prepared.
- **Special warnings relating to using the medicine in the target animals**

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Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin and may decrease its effectiveness.

Product usage should be based on bacteria susceptibility testing.

- **Special warnings relating to the safety of humans handling the product**

The product contains an active ingredient from the penicillin family.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may be serious.

. Do not handle this product if you know you are sensitive (allergic) to penicillins or cephalosporins.

Use this product with extreme caution in order to avoid exposure. Do not smoke, eat or drink when handling the medicine.

When preparing and administering the drinking water containing the medicine, avoid contact with the skin or inhaling this product.

Always use a face mask to avoid inhaling the product, protective clothing and gloves to prevent direct contact with the skin. Wash hands immediately after use.

In the event of contact with the skin or eyes, rinse with large amounts of water.

If reactions appear, such as irritation or skin rash, consult a doctor and show him the package. In the case of more serious reactions, such as swelling of the face, lips or eyes, or difficulty in breathing, seek medical attention immediately.

- **Using with egg-laying chickens**

Do not use the medicine on chickens that lay eggs for human consumption starting from 4 weeks before the onset of the egg-laying period. Use on breeding poultry shall be in accordance with the veterinarian's risk/benefit assessment.

- **Interaction with other medicines**

Do not use the product in combination with bacteriostatic antibiotics (such as tetracyclines). Synergies may take place in combination with beta-lactams and aminonoglycosides.

- Incompatibility

Do not mix this medicine with other veterinary medicines.

11. Storage instructions

- Prevent poisoning! This medicine, and any other medicine, must be kept in a closed place outside the reach of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store below 25°C in a dry place.
- Shelf life after first opening: 60 days.
- Shelf life after dilution according to the preparation instructions: 24 hours.

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

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

13. Additional information

In addition to the active ingredient, this medicine also contains: Sodium carbonate anhydrous, Silica colloidal anhydrous, Lactose anhydrous.

- What does the medicine look like and what is inside the package – a white or off-white powder.

- Package size: 1430 grams.
- Registration holder: Romet, Ltd., 39/104 Ha-Ma'apilim, Herzliya 46543
- Manufacturer:

Fatro S.P.A., Via Emilia 285 – 40064 Ozzano Emilia, Bologna, Italy

This leaflet was checked and approved by the Ministry of Health on: January 2018

Registration number of this medicine in the Ministry of Health State Medicine Registry: 143-31-92438-00.