

FLORFENIDEM 10%

100mg Florfenicol/ml, oral solution for poultry

STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Florfenidem 10% is a viscous, yellowish solution. Each ml of Florfenidem 10% contains: Florfenicol (active substance) 100 mg, Excipients ad.1 ml.

INDICATIONS

In poultry: for treatment of respiratory and digestive bacterial infections produced by susceptible bacteria: *Pasteurella multocida*, *Bordetella bronchiseptica*, *Salmonella spp.*, *Escherichia coli*, *Haemophilus paragallinarum*, *Staphylococcus spp.*, *Streptococcus spp.*, *Ornithobacterium rhinotracheale* and *Corynebacterium pyogenes*.

TARGET SPECIES: Poultry.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION The product is administered via drinking water poultry as following:

In poultry: the product is administered via drinking water in dosage of 20 mg/kg b.w.:

0.2 ml of product/kg b.w./day in birds under 4 weeks of age, and 0.4 ml of product/kg b.w./day in birds over 4 weeks of age, for 3 -5 days.

Based on the recommended doses and the number and weight of the animals to be treated, the exact daily amount of Florfenidem 10% should be calculated according to the following formula:

$$\frac{\text{ml Florfenidem 10\% / kg body weight/day} \times \text{mean body weight of animals to be treated (kg)}}{\text{Mean daily water consumption (liters) / animal}} = \text{ml Florfenidem 10\% / liter drinking water}$$

The uptake of medicated water is dependant on the clinical condition of animals. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted.

ADVICE ON CORRECT ADMINISTRATION: During treatment, the animals should drink only medicated water. If this is not possible the daily dosage must be divided in two and administered once in 12 hours. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

WITHDRAWAL PERIOD

For poultry meat: 2 days from the last administration. Not permitted for use in laying bird producing eggs for human consumption.

SPECIAL PRECAUTIONS FOR STORAGE

Keep away from reach and sight of children! Store in original packaging, at temperature below 25°C, protected from direct sunlight and freeze.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Shelf life after dilution in drinking water, according to directions: 24 hours.

Shelf-life after first opening of package: 28 days. Close tight the recipient after use. Do not use after expiry date which is stated on the label.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

For the environmental protection, medicines should not be disposed of via wastewater or household waste. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

OTHER INFORMATION

PE-HD flasks of 100 ml, 500 ml, and 1000 ml

PE-HD cans of 5 l, 10 l, and 20 l.

Not all pack sizes may be marketed.

For any information regarding this veterinary medicinal product, please contact the local representative of the marketing authorization holder.