

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 625 mg/g granules for use in drinking water for pheasants

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance :

Tylvalosin (as tylvalosin tartrate) 625 mg/g

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate

White granules.

3. CLINICAL INFORMATION

3.1 Target species

Pheasants

3.2 Indications for use for each target species

Treatment of respiratory disease associated with *Mycoplasma gallisepticum* in pheasants.

3.3 Contraindications

Do not use in cases of hypersensitivity to macrolide antibiotics or to any of the excipients.

3.4 Special warnings

Treat as soon as possible after clinical signs suggestive of mycoplasmosis are observed. Treat all the birds in the affected flock.

Cross-resistance has been shown between tylvalosin and other macrolides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to tylvalosin because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Good management and hygiene practices should be introduced to reduce the risk of re-infection.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Tylvalosin has been shown to cause hypersensitivity (allergic) reactions in laboratory animals; therefore, people with known hypersensitivity to tylvalosin should avoid contact with this product. When mixing the veterinary medicinal product and handling the medicated water, direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment consisting of impervious gloves and a half-mask respirator conforming to European Standard EN 149 or a nondisposable respirator conforming to European Standard EN 140 with a filter conforming to European Standard EN 143 should be worn when mixing the product. Wash contaminated skin.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds

The safety of the veterinary medicinal product has not been established during lay.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For use in drinking water.

The dose is 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days.

Determine the combined bodyweight (in kg) of all the birds to be treated. For example, one sachet of 40 g is sufficient to treat a total of 1,000 birds with an average bodyweight of 1 kg; one sachet of 400 g is sufficient to treat a total of 10,000 birds with an average bodyweight of 1 kg.

In order to achieve a correct dose, the preparation of a concentrated (stock) solution might be required (e.g. to treat a total of 500 kg total bird weight, only 50% of the prepared stock solution prepared from the 40 g sachet should be used).

The veterinary medicinal product should be added to a volume of water that the birds will consume in one day. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dose, the concentration of the veterinary medicinal product has to be adjusted accordingly. No other source of drinking water should be available during the medication period.

Mixing instructions:

The veterinary medicinal product may be mixed directly into the drinking water system or first mixed as a stock solution into a smaller amount of water, which is then added into the drinking water system.

When mixing the veterinary medicinal product directly into the drinking water system, the contents of the sachet should be sprinkled onto the surface of the water and mixed thoroughly until a clear solution is produced (usually within 3 minutes).

When preparing a stock solution, the maximum concentration should be 40 g of product per 1,500 ml of water and it is necessary to mix the solution for 10 minutes. After this time, any remaining cloudiness will not affect efficacy of the product.

Only a sufficient amount of medicated drinking water should be prepared to cover the daily requirements.

Medicated drinking water should be replaced every 24 hours.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No signs of intolerance have been observed in poultry species at up to 150 mg tylvalosin per kg bodyweight per day for 5 days.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Meat and offal: 2 days.

Do not release pheasants for at least two days after the end of medication.

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

Do not use within 14 days before the start of the laying period.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01FA92

4.2 Pharmacodynamics

Tylvalosin is a macrolide antibiotic. Macrolides are metabolites or derivatives of metabolites of soil organisms obtained by fermentation. They interfere with protein synthesis by reversibly binding to the 50S ribosome subunit. They are generally considered bacteriostatic.

Tylvalosin has activity against pathogenic organisms isolated from a range of animal species-mainly Gram-positive organisms and mycoplasma but also some Gram-negative organisms. Tylvalosin has activity against the following mycoplasma species found in poultry: *Mycoplasma gallisepticum*.

The minimum inhibitory concentration of tylvalosin for *Mycoplasma gallisepticum* ranges from 0.007 to 0.25 mcg/ml. Macrolides (including tylvalosin) have been shown to have effects on the innate

immune system, which may augment the direct effects of the antibiotic on the pathogen and aid the clinical situation.

Bacteria can develop resistance to antimicrobial substances. There are multiple mechanisms responsible for resistance development to macrolide compounds.

Cross-resistance within the macrolide group of antibiotics cannot be excluded. Reduced susceptibility for tylvalosin was generally noted in tylosin resistant strains.

4.3 Pharmacokinetics

Tylvalosin tartrate is rapidly absorbed after oral administration of the veterinary medicinal product. Tylvalosin is widely distributed in tissues with the highest concentrations found in the respiratory tissues, bile, intestinal mucosa, spleen, kidney and liver.

Tylvalosin has been shown to concentrate in phagocytic cells and gut epithelial cells. Concentrations (up to 12 times) were achieved in the cells (intracellular), compared to the extracellular concentration. *In vivo* studies have shown tylvalosin to be present in higher concentrations in the mucous lining of the respiratory and gut tissues compared to the plasma.

The major metabolite of tylvalosin is 3-acetyltalosin (3-AT), which is also microbiologically active.

The terminal half-lives for the elimination of tylvalosin and its active metabolite 3-AT range from 1 to 1.45 hours. Six hours after treatment, the concentration of tylvalosin in the gastrointestinal tract mucosa has a mean concentration of 133 ng/g and in the gastrointestinal contents of 1,040 ng/g. The active metabolite 3-AT has a mean concentration of 57.9 ng/g and 441 ng/g, respectively

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:

40 g sachet – 3 years.

400 g sachet – 2 years.

Shelf life after first opening the immediate packaging: 5 weeks.

Shelf life of the medicated drinking water: 24 hours.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Aluminium foil laminated sachet containing 40 g, or 400 g of granules.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/044/012 – 40 g

EU/2/04/044/014 – 400 g

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/09/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).