PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Aluminium Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 625 mg/g granules for use in drinking water for chickens and turkeys

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tylvalosin (as tylvalosin tartrate) 625 mg/g

3. PACKAGE SIZE

40 g
400 g

4. TARGET SPECIES

Chickens and Turkeys

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

In drinking water use

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 2 days.
Eggs: zero days

Turkeys: Not for use in birds producing eggs for human consumption.
Do not use within 21 days of the start of the laying period.

8. EXPIRY DATE

Exp. {mm/yyyy}
Medicated drinking water should be replaced every 24 hours.
Once opened use within 5 weeks

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

ECO Animal Health Ltd
The Grange
100 High Street
London
N14 6BN
United Kingdom

14. MARKETING AUTHORISATION NUMBERS

Vm 13277/5002

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal
Read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 625 mg/g granules for use in drinking water for chickens and turkeys

2. COMPOSITION

Active substance:
Tylvalosin (as tylvalosin tartrate) 625 mg/g.

White granules.

3. TARGET SPECIES

Chickens and turkeys

4. INDICATIONS FOR USE

Chickens
Treatment and metaphylaxis of respiratory infections caused by *Mycoplasma gallisepticum* in chickens. The presence of the disease in the flock should be established before metaphylactic treatment.

As an aid in reducing the development of clinical signs and mortality from respiratory disease in flocks, where infection *in ovum* with *Mycoplasma gallisepticum* is likely because the disease is known to exist in the parent generation.

Turkeys
Treatment of respiratory disease associated with tylvalosin sensitive strains of *Ornithobacterium rhinotracheale* in turkeys.

5. CONTRAINDICATIONS

None

6. SPECIAL WARNINGS

Special warnings:

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

Special precautions for safe use in the target species:

The strategy for *Mycoplasma gallisepticum* infection should include efforts to eliminate the pathogen from the parent generation.

Infection with *Mycoplasma gallisepticum* is reduced but not eliminated at the recommended dose.

Medication should only be used for short-term amelioration of clinical signs in breeder flocks whilst awaiting confirmation of diagnosis of *Mycoplasma gallisepticum* infection.

It is sound clinical practice to base treatment on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria.

Use of the product deviating from the instructions may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with other macrolides due to potential for cross-resistance.

In field studies investigating the effect of treatment and metaphylaxis on mycoplasmosis, all birds (approximately 3 weeks old) received the product when clinical signs were evident in 2 - 5% of the flock. At 14 days after initiation of treatment, 16.7 - 25.0% morbidity and 0.3 - 3.9% mortality were observed in the treated group in comparison to 50.0 - 53.3% morbidity and 0.3 - 4.5% mortality in an untreated group.

In further field studies, chicks from parent stock with evidence of *Mycoplasma gallisepticum* infection were administered the product for the first three days of life followed by a second course at 16 - 19 days of age (a period of management stress). By 34 days after the initiation of treatment, 17.5 - 20.0% morbidity and 1.5 - 2.3% mortality were observed in the treated groups in comparison to 50.0 - 53.3% morbidity and 2.5 - 4.8% mortality in the untreated groups.

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 non-disposable 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.

Laying birds:

The product can be used in chickens laying eggs for human consumption and breeding birds producing eggs for hatching broiler stock or replacement layers. The safety of the veterinary medicinal product has not been established during lay in turkeys.

Overdose (symptoms, emergency procedures, 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.

No adverse effects on egg production, egg fertility, hatchability and chick viability were observed in broiler breeder stock administered 75 mg tylvalosin per kg bodyweight per day for 28 consecutive days.

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

7. ADVERSE EVENTS

Chickens and turkeys.

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For use in drinking water.

Chickens
For treatment of respiratory disease associated with *Mycoplasma gallisepticum:*
The dose is 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days.

When used as an aid in reducing the development of clinical signs and mortality (where infection *in ovum* with *Mycoplasma gallisepticum* is likely):
The dose is 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days at 1 day old. This is followed by a second treatment with 25 mg tylvalosin per kg bodyweight per day in drinking water for 3 consecutive days at the period of risk, i.e. at times of management stress such as administration of vaccines (typically when birds are 2–3 weeks old).

Determine the combined bodyweight (in kg) of all the chickens to be treated. Select the correct number of sachets according to the amount of product required.

One sachet of 40 g is sufficient for a total of 1,000 kg of chickens (e.g. 20,000 birds with an average bodyweight of 50 g). One sachet of 400 g is sufficient to treat a total of 10,000 kg of chickens (e.g. 20,000 birds with an average bodyweight of 500 g).

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 product should be added to a volume of water that the chickens will consume in one day. No other source of drinking water should be available during the medication period.

Turkeys
For treatment of respiratory disease associated with tylvalosin-sensitive strains of *Ornithobacterium rhinotracheale:*
The dose is 25 mg tylvalosin per kg bodyweight per day in drinking water for 5 consecutive days.

Determine the combined bodyweight (in kg) of all the turkeys to be treated. Select the correct number of sachets according to the amount of product required.

One sachet of 40 g is sufficient for a total of 1,000 kg of turkeys (e.g. 10,000 birds with an average bodyweight of 100 g). One sachet of 400 g is sufficient to treat a total of 10,000 kg of turkeys (e.g. 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 product should be added to a volume of water that the turkeys will consume in one day. No other source of drinking water should be available during the medication period.

9. ADVICE ON CORRECT ADMINISTRATION

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 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 per 1,500 ml or 400 g of product per 15 litres water and it is necessary to mix the solution for 10 minutes. After this time, any remaining cloudiness will not affect the efficacy of the veterinary medicinal 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.

10. WITHDRAWAL PERIODS

Meat and offal: 2 days.
Eggs (chicken): zero days.

Turkeys: Not for use in birds producing eggs for human consumption.
Do not use within 21 days of the start of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”.
Shelf life after first opening the immediate packaging: 5 weeks.
Shelf life of the medicated drinking water: 24 hours

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V	Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes: Sachet of 40g or 400g.
Not all pack sizes may be marketed.
Vm 13277/5002

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

ECO Animal Health Limited
The Grange,
100 The High Street
London N14 6BN
Tel: +44 (0) 20 8447 8899
Email: sales@ecoanimalhealth.com

Manufacturer responsible for batch release:
Cod Beck Blenders Limited
Cod Beck Estate, Dalton, Thirsk
North Yorkshire,
YO7 3HR, United Kingdom.

17. OTHER INFORMATION

For animal treatment only.

Gavin Hall
Approved: 24 June 2025