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 pheasants

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tylvalosin (as tylvalosin tartrate) 625 mg/g

3. PACKAGE SIZE

40 g
400 g

4. TARGET SPECIES

Pheasants

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

In drinking water use

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 2 days.
Not for use in birds producing eggs for human consumption.

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 13277/5003

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 pheasants

2. COMPOSITION

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

White granules.

3. TARGET SPECIES

Pheasants

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

None

6. SPECIAL WARNINGS

Special warnings:

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

Special precautions for safe use in the target species:

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

Use of the product should be based 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 the 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 the potential for cross-resistance.

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:

Use only in accordance with benefit-risk assessment by the responsible veterinarian.

Overdose:

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

Pheasants.

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.

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 1kg.

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

Not for use in birds producing eggs for human consumption.
Do not use within 14 days of the start of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”.

Shelf life after 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 13277/5003

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: 01 December 2024