PARTICULARS TO APPEAR ON THE OUTER PACKAGE {BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 42.5 mg/g premix for medicated feeding stuff for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tylvalosin (as tylvalosin tartrate) 42.5 mg/g

3. PACKAGE SIZE

20 kg
5 kg
2 kg

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

In-feed use. For incorporation into dry feed only.
Mixing Instructions:
A horizontal ribbon mixer should be used to incorporate the veterinary medicinal product into feeding stuff. It is recommended that Aivlosin® is first mixed with 10 kg of the feeding stuff, followed by the rest of the feeding stuff and mixed well. Medicated feed may then be pelleted. Pelleting conditions involve a single pre-conditioning step with steam for 5 minutes and pelleting at not more than 70°C under normal conditions.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 2 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after incorporation into meal or pelleted feed: 1 month.
Once opened use within 4 weeks

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 C
Store in the original container
Keep the bag tightly closed.

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 13277/5000

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

Consideration should be given to official guidance on the incorporation of medicated premixes in final feed.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 42.5 mg/g premix for medicated feeding stuff for pigs

2. COMPOSITION

Active substance:
Tylvalosin (as tylvalosin tartrate) 42.5 mg/g.

A beige granular powder.

Carrier: Hydrated magnesium silicate, wheat flour.

3. TARGET SPECIES

Pigs

4. INDICATIONS FOR USE

Treatment and metaphylaxis of swine enzootic pneumonia caused by susceptible strains of *Mycoplasma hyopneumoniae*. At the recommended dose, lung lesions and weight loss are reduced but infection with *Mycoplasma hyopneumoniae* is not eliminated.
Treatment of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis* in herds where there is a diagnosis based on clinical history, post-mortem findings and clinical pathology results.
Treatment and metaphylaxis of swine dysentery in herds, caused by *Brachyspira hyodysenteriae,* where the disease has been diagnosed.

5. CONTRAINDICATIONS

None

6. SPECIAL WARNINGS

Special warnings:

Acute cases and severely diseased pigs with reduced food or water intake should be treated with a suitable injectable product.

Generally, strains of *B. hyodysenteriae* have higher minimal inhibitory concentration (MIC) values in cases of resistance against other macrolides, such as tylosin. The clinical relevance of this reduced susceptibility is not fully explored. Cross-resistance between tylvalosin and other macrolides cannot be excluded.

Special precautions for safe use in the target species:

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

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 premix, 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.

Pregnancy and lactation:

The safety of Aivlosin during pregnancy and lactation has not been established in pigs. Use only in accordance with benefit-risk assessment by the responsible veterinarian.
Laboratory studies in animals have not produced any evidence of a teratogenic effect. Maternal toxicity in rodents has been observed at doses of 400 mg tylvalosin per kg bodyweight and above. In mice, a slight reduction in the foetal bodyweight was seen at doses causing maternal toxicity.

Overdose:

No signs of intolerance have been observed in growing pigs at up to 10 times the recommended dose.

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

7. ADVERSE EVENTS

Pigs.

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

In-feed use.
For incorporation into dry feed only.

For treatment and metaphylaxis of swine enzootic pneumonia:
The dose is 2.125 mg tylvalosin per kg bodyweight per day in-feed for 7 consecutive days. Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

For treatment of porcine proliferative enteropathy (ileitis):
The dose is 4.25 mg tylvalosin per kg bodyweight per day in-feed for 10 consecutive days.

For treatment and metaphylaxis of swine dysentery:
The dose is 4.25 mg tylvalosin per kg bodyweight per day in-feed for 10 consecutive days.

Indication	Dose of active ingredient	Duration of treatment	In feed inclusion rate
Treatment and metaphylaxis of swine enzootic pneumonia	2.125 mg/kg bodyweight/day	7 days	1 kg/tonne*
Treatment of PPE (ileitis)	4.25 mg/kg bodyweight/day	10 days	2 kg/tonne*
Treatment and metaphylaxis of swine dysentery	4.25 mg/kg bodyweight/day	10 days	2 kg/tonne*

* **Important**: these inclusion rates assume a pig eats the equivalent of 5% bodyweight per day.

In older pigs, or in pigs with reduced appetite, or on restricted feed intake, inclusion levels may need to be increased to achieve target dose. Where feed intake is reduced, use the following formula:

$$\text{Kg premix/tonne feed} = \frac{\text{Dose rate (mg/kg bodyweight) x bodyweight (kg)}}{\text{Daily feed intake (kg) x Premix strength (mg/g)}}$$

Acute cases and severely diseased pigs with reduced food and water intake should be treated with a suitable injectable product.

In addition to medical treatment, good management and hygiene practices should be established on the farm in order to reduce the risk of infection and to control the build-up of resistance.
The medicated feed should be fed as the sole ration.

9. ADVICE ON CORRECT ADMINISTRATION

Mixing instructions:
A horizontal ribbon mixer should be used to incorporate the veterinary medicinal product into feeding stuff. It is recommended that Aivlosin is first mixed with 10 kg of the feeding stuff, followed by the rest of the feeding stuff and mixed well. Medicated feed may then be pelleted. Pelleting conditions involve a single pre-conditioning step with steam for 5 minutes and pelleting at not more than 70 □C under normal conditions.

10. WITHDRAWAL PERIODS

Meat and offal: 2 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30 °C.
Store in the original container.
Keep the container tightly closed.
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: 4 weeks.
Shelf life after incorporation into feed: meal and pellets: 1 month.

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: Bag of 2 kg, 5 kg or 20 kg.
Not all pack sizes may be marketed.
Vm 13277/5000

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.

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

Gavin Hall
Approved: 01 December 2024