PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE/INNER BAG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 42.5 mg/g premix for medicated feeding stuff for pigs
Tylvalosin (as tylvalosin tartrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Tylvalosin (as tylvalosin tartrate) 42.5 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

20 kg
5 kg
2 kg

5. TARGET SPECIES

Pigs

6. INDICATIONS

7. METHOD AND ROUTE 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.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 2 days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after incorporation into meal or pelleted feed: 1 month.
Shelf life after first opening of the immediate packaging: 4 weeks

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 13277/5000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Cod Beck Blenders Limited
Cod Beck Estate
Dalton Lane, Dalton
Thirsk, North Yorkshire
YO7 3HR
United Kingdom
or
Acme Drugs s.r.l.
Via Portella della Ginestra 9/a
42025 CAVRIAGO (RE)
ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 42.5 mg/g premix for medicated feeding stuff for pigs
Tylvalosin (as tylvalosin tartrate)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

A beige granular powder.

Carrier:
Hydrated magnesium silicate, wheat flour.

4. INDICATIONS

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. ADVERSE REACTIONS

None known.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE 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 PERIOD(S)

Meat and offal: 2 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30 °C.
Keep the container tightly closed.
Store in the original container.

Shelf life after first opening the immediate packaging: 4 weeks.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”.

Shelf life after incorporation into feed: meal and pellets: 1 month.

12. SPECIAL WARNINGS

Special warnings for each target species:

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 use in animals:

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 (symptoms, emergency procedures, antidotes):
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

Available in pack sizes containing 2 kg, 5 kg or 20 kg of product.

Not all pack sizes may be marketed. Consideration should be given to official guidance on the incorporation of medicated premixes in final feed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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100 The High Street
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Email: sales@ecoanimalhealth.com

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