SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aivlosin 42.5 mg/g oral powder for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral powder
A beige granular powder

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

- Treatment and metaphylaxis of swine enzootic pneumonia caused by susceptible strains of *Mycoplasma hyopneumoniae* in pigs. 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, caused by *Brachyspira hyodysenteriae* in herds where the disease has been diagnosed.

4.3 Contraindications

None

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

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 in the SPC 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.

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

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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pigs.

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 also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in pigs. Use only according to the 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

For use in individual pigs on farms where only a small number of pigs are to receive the treatment. Larger groups should be treated with medicated feeding stuff containing the premix.

For treatment and metaphylaxis of swine enzootic pneumonia
The dose is 2.125 mg tylvalosin per kg bodyweight per day 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 for 10 consecutive days.

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

This is achieved by thoroughly mixing Aivlosin into approximately 200–500 g of feed and then thoroughly mixing this pre-mixture into the remainder of the daily ration.
scoops of 2 sizes are provided for measuring the correct amount of Aivlosin for mixing with the daily ration, according to the schedule below. The feed containing the oral powder should be provided as the sole ration for the periods recommended above.

The pig to be treated should be weighed and the amount of feed that the pig is likely to consume should be estimated, based on a daily feed intake equivalent to 5% of bodyweight. Consideration must be given to pigs whose daily feed intake is reduced or restricted. The correct quantity of Aivlosin should be added to the estimated quantity of daily ration for each pig, in a bucket or similar receptacle, and thoroughly mixed.
The veterinary medicinal product should only be added to dry non-pelleted feed.

Swine enzootic pneumonia 2.125 mg/kg bodyweight		
Bodyweight range (kg)	**Scoop size**	**Number of scoops**
7.5–12	1 ml	1
13–25	1 ml	2
26–38	1 ml	3
39–67	5 ml	1
68–134	5 ml	2
135–200	5 ml	3
201–268	5 ml	4

PPE (ileitis) and swine dysentery 4.25 mg/kg bodyweight		
Bodyweight range (kg)	**Scoop size**	**Number of scoops**
7.5–12	1 ml	2
13–19	1 ml	3
20–33	5 ml	1
34–67	5 ml	2
68–100	5 ml	3
101–134	5 ml	4
135–200	5 ml	6
201–268	5 ml	8

NB: A level scoop of the product should be measured.

As an adjunct to medication, good management and hygiene practices should be introduced in order to reduce the risk of infection and to control the potential build-up of resistance.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Meat and offal: 2 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

ATCvet code:
QJ01FA92
Pharmacotherapeutic group: antibacterials for systemic use, macrolides.

5.1 Pharmacodynamic properties

Tylvalosin tartrate is a macrolide antibiotic that has antibacterial activity against Gram-positive, some Gram-negative organisms and mycoplasma. It acts by inhibiting protein synthesis in bacteria cells.

Macrolide antibiotics are metabolites or semi-synthetic derivatives of metabolites of soil organisms obtained by fermentation. They have differently sized lactone rings and are basic due to the dimethylamino group. Tylvalosin has a sixteen-membered ring.

Macrolides interfere with protein synthesis by reversibly binding to the 50S ribosome subunit. They bind to the donor site and prevent the translocation necessary for keeping the peptide chain growing. Their effect is essentially confined to rapidly dividing organisms. Macrolides are generally considered bacteriostatic and mycoplasmastatic.

It is considered that there are multiple mechanisms responsible for resistance development to macrolide compounds, namely alteration of the ribosomal target site, utilisation of active efflux mechanism and production of inactivating enzymes.

Resistance to tylvalosin *by Mycoplasma hyopneumoniae* and *Lawsonia intracellularis* has not been reported or found in the field to date. No breakpoint for *Brachyspira hyodysenteriae* has been established. Generally, strains of *B. hyodysenteriae* have higher 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 macrolide antibiotics cannot be excluded.

5.2 Pharmacokinetic particulars

Tylvalosin tartrate is rapidly absorbed after oral administration of Aivlosin.

After administration of the recommended dose lung concentrations of 0.060–0.066 µg/ml were found at 2 and 12 hours post-treatment. The parent compound is widely distributed in the tissues with the highest concentrations found in the lungs, bile, intestinal mucosa, spleen, kidney and liver.

There is evidence that the concentration of macrolides is higher at the site of infection than in plasma, in particular in neutrophils, alveolar macrophages and alveolar epithelial cells.

In vitro metabolism studies have confirmed that the parent compound is rapidly metabolised to 3-*O*- acetyltylosin. In a trial with ^{14}C-Aivlosin administered at 2.125 mg/kg to pigs for 7 days, over 70% of the dose was

excreted in the faeces, with urinary excretion accounting for 3 to 4% of the dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wheat flour
Hydroxypropyl cellulose
Non-fat soyabean powder
Hydrated magnesium silicate (sepiolite)

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening of the immediate packaging: 4 weeks.
Feed to which the oral powder has been added should be replaced if not consumed within 24 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

One aluminium foil/polyester laminated bag containing 500 g. Scoops of 1 ml and 5 ml are attached.

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

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 13277/5001

9. DATE OF FIRST AUTHORISATION

09 September 2004

10. DATE OF REVISION OF THE TEXT

July 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 01 December 2024