



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/63817/2006
EMA/V/C/000083

Aivlosin (*tylvalosin*)

An overview of Aivlosin and why it is authorised in the EU

What is Aivlosin and what is it used for?

Aivlosin is an antibiotic used to treat a number of infectious diseases in pigs, chickens, pheasants and turkeys.

In pigs, Aivlosin is used to treat and for metaphylaxis of several infections caused by bacteria that affect the lungs (i.e. swine enzootic pneumonia) or the intestinal tract (swine dysentery or porcine proliferative enteropathy). Metaphylaxis means giving a medicine to a group of animals, aiming to treat animals sick with an infection while controlling spread of the infection among the rest, some of whom may already be infected. Aivlosin improves the health and weight of the animals but it may not eliminate completely the bacteria that caused lung infection.

In chickens and pheasants, Aivlosin is used for treatment and metaphylaxis of lung infections caused by the bacterium *Mycoplasma gallisepticum*.

In turkeys, Aivlosin is used to treat lung infections caused by a bacterium, *Ornithobacterium rhinotracheale*, which can cause illness when it is complicated by other viral and bacterial infections.

Aivlosin contains the active substance tylvalosin (previously called acetylisovaleryltylosin).

How is Aivlosin used?

The medicine can only be obtained with a prescription. Aivlosin is available as a premix for medicated feeding stuff and as an oral powder for pigs, and as granules for use in drinking water for pigs, chickens, turkeys and pheasants.

Aivlosin premix can only be used by an authorised feed mill to prepare medicated feed, which is then distributed to the farmer to treat a large number of pigs. Aivlosin oral powder is mixed into pig feed by the animal owner and is used to treat individual pigs. Aivlosin granules are added to the drinking water system, either directly or after dilution into a stock solution.

For more information about using Aivlosin, see the package leaflet or contact your veterinarian or pharmacist.



How does Aivlosin work?

The active substance of Aivlosin, tylvalosin, is an antibiotic of the macrolide group. It works by blocking the bacteria's ribosomes, the parts of the cell where proteins are produced, and so inhibits the growth of bacteria.

What benefits of Aivlosin have been shown in studies?

The antimicrobial effectiveness of tylvalosin against bacteria that cause diseases was investigated in the laboratory. The main clinical studies on the effectiveness of Aivlosin were carried out on farms in several countries within and outside the EU.

The studies in pigs involved either pigs already affected by the disease or pigs likely to develop the disease because they were in contact with diseased animals on the same farm. The studies showed that pigs treated with Aivlosin had less severe signs of disease than untreated animals. Treatment success with Aivlosin was similar to that with other medicines of the same class authorised for such diseases in pigs.

Further studies investigated Aivlosin in diseased chickens and pheasants as well as in very young chicks that hatched from eggs from flocks where the disease was present. Chickens and pheasants treated with Aivlosin had less severe signs of disease than untreated animals. The effectiveness of Aivlosin was similar to that of other medicines of the same class already authorised for this disease in chickens. The treatment did not eliminate all bacteria in the respiratory system and some birds still showed the disease; however, the number of affected animals was significantly smaller than in an untreated group of birds.

In turkeys only laboratory studies were performed. These included a dose confirmation study in turkey poults (young turkeys) artificially infected with a lung virus (avian pneumovirus) and *Ornithobacterium rhinotracheale*, to simulate a complicated infection. Poults either received treatment with Aivlosin or no treatment. The main measure of effectiveness was damage to lungs and air sacs, which was less for the Aivlosin-treated turkeys than for the untreated group.

What is the risk associated with Aivlosin?

For the full list of restrictions of Aivlosin, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

People who have had reactions when handling Aivlosin or similar products should avoid any contact with Aivlosin.

When mixing Aivlosin into feed or drinking water or handling the medicated feed or water, direct contact with eyes, skin and mouth should be avoided and protective equipment should be worn, e.g. overalls, gloves and face masks (respirator). Skin that has been in contact with Aivlosin or feed or drinking water that contains Aivlosin should be washed.

Aivlosin should not be used in people. If a person accidentally consumes Aivlosin, immediate medical advice should be sought and the package leaflet or label shown to the doctor.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after giving the medicine and before the animal can be slaughtered and the meat used for human consumption. It is also the time required after giving a medicine before eggs may be used for human consumption.

The withdrawal period for meat from pigs, chickens, turkeys and pheasants treated with Aivlosin is 2 days.

The withdrawal period for eggs from chickens treated with Aivlosin is zero days. The medicine is not authorised for use in turkeys producing eggs for human consumption. It should not, therefore, be used in laying turkeys nor for 3 weeks before turkeys are likely to start laying eggs for human consumption.

Why is Aivlosin authorised in the EU?

The European Medicines Agency decided that Aivlosin's benefits are greater than its risks and that it can be authorised for use in the EU.

Other information about Aivlosin

Aivlosin received a marketing authorisation valid throughout the EU on 9 September 2004.

Further information on Aivlosin can be found on the Agency's website:

ema.europa.eu/medicines/veterinary/EPAR/aivlosin

This summary was last updated in 06-2020.