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Tulinovet (*tulathromycin*)

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

What is Tulinovet and what is it used for?

Tulinovet is an antibiotic medicine that is used to treat the following diseases if they are caused by bacteria that are susceptible to it:

- bovine respiratory disease (BRD) in cattle caused by *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis*;
- infectious bovine keratoconjunctivitis (IBK) in cattle, an eye disease caused by *Moraxella bovis*;
- swine respiratory disease (SRD) in pigs caused by *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma hyopneumoniae*, *Haemophilus parasuis* and *Bordetella bronchiseptica*;
- early stages of foot rot in sheep caused by *Dichelobacter nodosus*, which requires treatment with a medicine given by mouth or by injection.

Tulinovet can also be used for metaphylaxis of BRD and SRD. This involves treating at the same time both diseased animals and healthy animals in close contact with them, to prevent further spread of the disease. The medicine should only be used for metaphylaxis in cattle and pigs once presence of the disease in the herd has been established.

Tulinovet contains the active substance tulathromycin.

Tulinovet is a 'generic medicine'. This means that Tulinovet contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Draxxin.

For more information, see the package leaflet.

How is Tulinovet used?

The medicine can only be obtained with a prescription. Tulinovet is available as an injection (100 mg/ml).

Tulinovet is given as a single injection of 2.5 mg per kilogram bodyweight. It is injected under the skin in cattle and into the neck muscle in pigs and sheep. Depending on the size of the dose, it may need to be injected into two sites.

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It is recommended that animals are treated early for respiratory disease and that their response is evaluated within 48 hours. If symptoms persist, get worse or come back, treatment should be changed to another antibiotic.

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

How does Tulinovet work?

The active substance in Tulinovet, tulathromycin, is an antibiotic that belongs to the class 'macrolides'. It works by attaching to the RNA (genetic material) in the bacterial cells and preventing the bacteria from making vital proteins, thus stopping them growing and multiplying.

Tulinovet is effective against the bacteria that most commonly cause BRD, SRD, IBK and foot rot.

How has Tulinovet been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Draxxin, and do not need to be repeated for Tulinovet.

As for every medicine, the company provided studies on the quality of Tulinovet. There was no need for 'bioequivalence' studies to investigate whether Tulinovet is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Tulinovet is very similar to the reference medicine and when given by injection under the skin to cattle or into a muscle in pigs and sheep, the active substance in both products is expected to be similarly absorbed and the products are expected to have the same effects.

What are the benefits and risks of Tulinovet?

Because Tulinovet is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Tulinovet, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers. The precautions are the same as for the reference medicine since Tulinovet is a generic medicine.

What is the withdrawal period in food-producing animals?

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

For cattle the meat withdrawal period is 22 days, for pigs it is 13 days and for sheep it is 16 days. Tulinovet must not be used in animals that are producing milk for human consumption, or in pregnant animals intended to produce milk for human consumption, within two months of their expected date of giving birth.

Why is Tulinovet authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Tulinovet has been shown to be comparable to Draxxin. Therefore, the Agency's view was that, as for Draxxin, the benefit of Tulinovet outweighs the identified risk and it can be authorised for use in the EU.

Other information about Tulinovet

Tulinovet received a marketing authorisation valid throughout the EU on 16/09/2020.

Further information on Tulinovet can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/tulinovet.

Information on the reference medicine can also be found on the Agency's website.

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