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EPAR summary for the public

Draxxin

tulathromycin

This is a summary of the European Public Assessment Report (EPAR) for Draxxin. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use.

For practical information about using Draxxin, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Draxxin and what is it used for?

Draxxin is an antibiotic medicine that contains the active substance tulathromycin. Draxxin is used to treat the following diseases if they are caused by bacteria that are sensitive to tulathromycin:

- 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 systemic treatment (treatment with a medicine given by mouth or by injection).

Draxxin can also be used for metaphylaxis of BRD and SRD. This means to treat at the same time both diseased animals and those clinically healthy animals in close contact with them, to prevent them from developing clinical signs and to prevent further spread of the disease. The medicine should only be used for metaphylaxis in cattle and pigs once the presence of the disease in the

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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herd has been established, and if animals are expected to develop the disease within two to three days.

Draxxin is given as a single injection of 2.5 mg per kilogram bodyweight. In cattle, it is injected under the skin, and the dose is divided in cattle weighing over 300 kg so that no more than 7.5 ml are injected at one site. In pigs it is injected into a muscle, and the dose is divided in pigs weighing over 80 kg so that no more than 2 ml are injected at one site. It is recommended that animals are treated in the early stages of 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.

In sheep, Draxxin is injected into the neck muscle. For the best results sheep with foot rot should be kept in a dry environment.

Draxxin is available as a solution for injection (25 mg/ml and 100 mg/ml). The 25 mg/ml solution for injection is for pigs only whilst the 100 mg/ml solution for injection is for cattle, pigs and sheep.

How does Draxxin work?

The active substance in Draxxin, tulathromycin, is an antibiotic that belongs to the class 'macrolides'. It works by attaching to the RNA (the molecules that instruct the cell how to make proteins) within the bacterial cells. This prevents the bacteria being able to make vital proteins and stops them growing and multiplying. Draxxin is effective against the bacteria that most commonly cause BRD, SRD, IBK and foot rot. However, some bacteria can develop resistance against tulathromycin, which will reduce its effectiveness. Antibiotic resistance is the ability of bacteria to grow in the presence of an antibiotic that would normally kill them or limit their growth. This means that the antibiotic may no longer work on bacteria infecting either animals or humans.

What benefits of Draxxin have been shown in studies?

The effectiveness of Draxxin in treating or preventing BRD was studied in nine main studies involving calves, carried out during an outbreak of the disease. In the treatment studies, the cattle were infected with BRD-causing bacteria, but the cattle in the prevention studies had no symptoms of the disease. Draxxin was compared with tilmicosin or florfenicol (other antibiotics), and, in the prevention studies also with placebo (a dummy treatment). The main measure of effectiveness was the change in symptoms, including body temperature, breathing and recovery over a period of between two weeks and two months.

For the treatment of IBK, the effectiveness of Draxxin has been studied in three main studies involving calves. In two studies, it was compared with placebo, and the third study also compared it with oxytetracycline (another antibiotic). The main measure of effectiveness was the proportion of cattle whose disease was cured after three weeks. In two of the three studies of IBK, Draxxin was more effective than placebo in curing the disease. However, the third study found no difference between the effectiveness of Draxxin, oxytetracycline and placebo. The reasons for this are not clear.

The effectiveness of Draxxin in treating SRD has been studied in pigs in two main studies, where it was compared with the antibiotics tiamulin or florfenicol. The main measure of effectiveness was the change in symptoms over 10 days. For the metaphylaxis of SRD, the effectiveness of Draxxin was studied in six main studies, in which it was compared with placebo. The main measure of effectiveness was the proportion of pigs that completed the full three or six weeks of each study without needing to be removed from the study because of SRD. A third study involved pigs with

SRD with *Bordetella bronchiseptica* present. Treatment with Draxxin was compared to another antibiotic, tildipirosin. The main measure of effectiveness was clinical cure rate (no SRD or mild SRD) on day 14.

A single 2.5 mg/kg dose of Draxxin was effective in treating and preventing further outbreak of BRD in cattle and SRD in pigs. In all studies, Draxxin was at least as effective as the comparator medicines. Looking at the studies taken together, it was more effective than placebo.

For effectiveness in treating foot rot in sheep, Draxxin was compared to tilmicosin in a study involving 477 sheep with typical signs of foot rot (foul smell, damaged tissue between the claws of at least one foot and lameness). Two weeks after treatment 84% of Draxxin-treated sheep were successfully treated compared to 82% of tilmicosin-treated sheep. Draxxin was as effective as tilmicosin in treating the early stages of severe foot rot.

What are the risks associated with Draxxin?

Temporary pain and swelling at the injection site in cattle can last up to 30 days after subcutaneous injection. This has not been seen in pigs and sheep after intramuscular injection. Other types of reaction to the injection persist for about 30 days after injection in cattle and pigs.

The most common side effects with Draxxin in sheep (which may affect more than 1 in 10 sheep) are short lived signs of discomfort (head shaking, rubbing the injection site and backing away) lasting only a few minutes.

Draxxin should not be used in animals that are hypersensitive (allergic) to macrolide antibiotics. It should also not be used at the same time as other macrolide antibiotics or lincosamides (another type of antibiotic medicine).

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

Draxxin can cause eye irritation. If Draxxin accidentally gets into the eyes, they should be flushed immediately with clean water. Draxxin may also cause sensitisation (redness, itching and swelling) if it comes into contact with the skin. If accidental skin exposure occurs, the skin should be washed immediately with soap and water. Hands should be washed after use. In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

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 can 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. Draxxin 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 Draxxin approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Draxxin's benefits are greater than its risks and recommended that it be approved in the EU.

Other information about Draxxin:

The European Commission granted a marketing authorisation valid throughout the EU for Draxxin on 23 July 2003.

The full EPAR for Draxxin can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/ European public assessment reports. For more information about treatment with Draxxin, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in September 2016.