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EPAR summary for the public

Zeleris

florfenicol / meloxicam

This is a summary of the European public assessment report (EPAR) for Zeleris. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Zeleris.

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

What is Zeleris and what is it used for?

Zeleris is a veterinary medicine used to treat cattle with bovine respiratory disease (BRD, a condition affecting the lungs) associated with a high temperature, which is due to the bacteria *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*. Zeleris contains the active substances florfenicol and meloxicam.

For further information, see the package leaflet.

How is Zeleris used?

The medicine can only be obtained with a prescription and is available as a solution for injection. The dose depends on the animal's weight and is given by injection under the skin in the neck area. Cattle weighing more than 150 kg will need to have the dose divided and injected at more than one site. As Zeleris contains an antibiotic it is essential to closely follow the instructions in the package leaflet to minimise the development of antibiotic resistance. 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.

For further information, see the package leaflet.

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How does Zeleris work?

Florfenicol is a broad-spectrum antibiotic which stops bacteria from growing by blocking the activity of ribosomes, the part of the bacterial cells where proteins are produced.

Meloxicam belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by blocking an enzyme called cyclooxygenase which is involved in the production of prostaglandins. As prostaglandins are substances that trigger inflammation, pain, exudation (fluid that leaks out of blood vessels during an inflammation) and fever, meloxicam reduces these signs of disease.

What benefits of Zeleris have been shown in studies?

In a field study 329 calves with bovine respiratory disease and a body temperature of 40°C or higher were treated either with Zeleris or florfenicol alone. Zeleris was as effective as florfenicol alone in improving signs of the disease (based on behaviour and breathing) on day 7. A success rate of 67% was achieved with Zeleris compared to 65% for florfenciol. In addition, in the first 48 hours after the injection, Zeleris was more effective than florfenicol alone in reducing the body temperature to below 39.5°C.

What are the risks associated with Zeleris?

The most common side effects with Zeleris (which may affect more than 1 in 10 animals) are reactions at the injection site (mostly swelling, hardness, heat and pain) after injection under the skin. These reactions are usually short lived and go away within 5 to 15 days but could last up to 49 days.

During injection of this product animals may show signs of moderate pain, such as movement of the head or neck.

Zeleris must not be given to bulls intended for breeding nor to animals with impaired liver, heart or kidney function, bleeding disorders or with gut ulceration.

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

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 Zeleris, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

People who are hypersensitive (allergic) to florfenicol, meloxicam or any of the other ingredients of the medicine should avoid contact with Zeleris.

In case of eye contact the affected area should be rinsed immediately with water.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Zeleris should not be administered by pregnant women.

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.

The withdrawal period for meat from cattle treated with Zeleris is 56 days.

The medicine is not authorised for use in cows producing milk for human consumption. It should also not be used in pregnant cows which are intended to produce milk for human consumption within two months of calving.

Why is Zeleris approved?

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

Other information about Zeleris:

The European Commission granted a marketing authorisation valid throughout the EU for Zeleris on 15 May 2017.

The full EPAR for Zeleris 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 Zeleris, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2017.