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EPAR summary for the public

Zactran

gamithromycin

This is a summary of the European public assessment report (EPAR) for Zactran. 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 Zactran.

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

What is Zactran and what is it used for?

Zactran is a type of antibiotic called a macrolide that is used to treat the following bacterial infections:

- bovine respiratory disease (BRD), a lung infection in cattle, caused by the bacteria *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*. Zactran can also be used metaphylactically, which means to treat at the same time both diseased cattle and healthy cattle in close contact with them, in order to prevent healthy animals from developing infection and so prevent further spread of the disease. When using Zactran for metaphylaxis of BRD, the presence of the disease in the herd should be established first;
- swine respiratory disease (SRD), a lung infection in pigs, caused by *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis* and *Bordetella bronchiseptica*;
- foot rot in sheep caused by *Dichelobacter nodosus* and *Fusobacterium necrophorum* needing systemic treatment (treatment reaching the bacteria via the blood stream, e.g. by injection).

Zactran contains the active substance gamithromycin. For further information, see the package leaflet.

How is Zactran used?

The medicine can only be obtained with a prescription and is available as a solution for injection.

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

Zactran is given as a single dose, by injection under the skin for cattle and sheep and into muscle for pigs. The dose to use is calculated according to the animal's weight. Cattle weighing more than 250 kg, and pigs and sheep weighing more than 125 kg, will need to have the dose divided and injected at more than one site.

When treating foot rot in sheep, appropriate flock management measures should be used, such as keeping sheep in a dry environment.

As Zactran is 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.

How does Zactran work?

The active substance of Zactran, gamithromycin, is an antibiotic of the macrolide group. It works by blocking the bacteria's ribosomes, which are parts of the cells where proteins are produced, and so prevents the bacteria from growing.

What benefits of Zactran have been shown in studies?

For the treatment of BRD, Zactran was studied in comparison to another macrolide antibiotic (tulathromycin) in cattle already affected by the disease. For the metaphylaxis of BRD, the effect of Zactran was studied in comparison to placebo (dummy treatment) in cattle which had been in contact with diseased animals on the same farm and, therefore, likely also to develop the disease. Zactran was shown to be effective in the treatment and metaphylaxis of BRD associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*. In the treatment of BRD, Zactran was shown to be as effective as tulathromycin.

For the treatment of SRD, a field study was conducted in pigs with SRD comparing Zactran to tildipirosin, another macrolide antibiotic. The main measures of effectiveness were respiratory and depression scores as well as body temperature. Treatment success was 97% in the Zactran-treated pigs compared to 93% in the tildipirosin group. A second field study in pigs with SRD compared Zactran to tulathromycin, however, in this study Zactran was not as effective as tulathromycin.

Zactran was as effective as tilmicosin in treating severe foot rot in sheep. In a study involving 364 sheep with typical signs of foot rot, 98% of Zactran-treated sheep were successfully treated after 3 weeks compared to 93% of tilmicosin-treated sheep based on lameness scores. As the efficacy of antimicrobial treatment of foot rot might be reduced by others factors, such as wet environmental conditions or inappropriate farm management, treatment of foot rot should therefore be undertaken along with other flock management tools.

What are the risks associated with Zactran?

Zactran must not be given to animals hypersensitive (allergic) to any macrolide, and must not be used at the same time as other macrolides or another type of antibiotic called lincosamides.

The most common side effects with Zactran in cattle (which may affect more than 1 in 10 cattle) are swellings at the site of injection. The cattle may also show signs of slight pain at the site of injection for one day. The swelling generally resolves in 3 to 14 days but may persist in some cattle for up to

35 days after treatment.

The most common side effects with Zactran in pigs and sheep (which may affect up to 1 in 10 animals) are mild to moderate swellings at the site of injection. These local reactions are short-lived and typically resolve within 2 days for pigs and 4 days for sheep.

For the full list of all side effects reported with Zactran, 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 Zactran, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Zactran. Zactran may cause irritation to the eyes or the skin. Therefore, contact with skin or eyes should be avoided. If Zactran comes in direct contact with the eyes, they should be flushed immediately with clean water. Similarly, if Zactran comes into direct contact with skin, the affected area should be washed immediately with clean water.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or the label should be presented 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 may be used for human consumption.

The withdrawal period is 64 days for meat from cattle, 16 days for meat from pigs and 29 days for meat from sheep treated with Zactran.

The medicine is not authorised for use in animals producing milk for human consumption. It should also not be used within 2 months of calving in pregnant cows and heifers intended to produce milk for human consumption or within 1 month of lambing in pregnant ewes intended to produce milk for human consumption.

Why is Zactran approved?

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

Other information about Zactran

The European Commission granted a marketing authorisation valid throughout the EU for Zactran on 24 July 2008. Information on the prescription status of this product may be found on the label/outer package.

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

This summary was last updated in December 2017.