



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Kriptazen (*halofuginone*)

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

What is Kriptazen and what is it used for?

Kriptazen is a medicine used to treat newborn calves to prevent or reduce diarrhoea caused by an organism called *Cryptosporidium parvum*. This is a parasite belonging to the 'protozoa' family that invades the digestive system, producing an infection called cryptosporidiosis that results in diarrhoea.

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

How is Kriptazen used?

Kriptazen can only be obtained with a prescription and is available as an oral solution (liquid to be given by mouth). It is given to newborn calves once a day for one week. For prevention of diarrhoea, treatment should start within 24 to 48 hours of birth; for reducing diarrhoea, treatment should start within 24 hours of the start of the diarrhoea. Kriptazen should be given after feeding.

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

How does Kriptazen work?

The active substance in Kriptazen, halofuginone lactate, prevents the growth of *Cryptosporidium parvum*. It also limits the spread of the disease by preventing the formation of oocysts, which are a stage in the lifecycle of the parasite where it is infectious and which are passed in the faeces. The exact way halofuginone works is unknown.

How has Kriptazen been studied?

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



every medicine, the company provided studies on the quality and manufacture of Kriptazen. No additional studies were needed as Kriptazen is a water based oral solution containing the same active substance and other ingredients as the reference medicine.

What are the benefits and risks of Kriptazen?

Because Kriptazen 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 Kriptazen, 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 Kriptazen 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.

The withdrawal period for meat from newborn calves treated with Kriptazen is 13 days.

Why is Kriptazen authorised in the EU?

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

Other information about Kriptazen

Kriptazen received a marketing authorisation valid throughout the EU on 8 February 2019.

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

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

This overview was last updated in December 2018.