



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Halocur (*halofuginone*)

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

What is Halocur and what is it used for?

Halocur is a veterinary medicine used to prevent or reduce diarrhoea caused by an organism called *Cryptosporidium parvum* in newborn calves. *C. parvum* is a parasite belonging to the 'protozoa' family that invades the digestive system, causing diarrhoea. The infection is known as cryptosporidiosis.

The medicine contains the active substance halofuginone.

How is Halocur used?

Halocur 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. Halocur should be given after feeding.

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

How does Halocur work?

The active substance in Halocur, halofuginone, prevents the growth of *C. 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 that are passed in the faeces. The exact way halofuginone works is unknown.

What benefits of Halocur have been shown in studies?

A number of field trials were performed involving calves from different farms. In one trial, calves aged from 4 to 10 days from 40 farms were included. Treatment with Halocur during 7 consecutive days was shown to reduce diarrhoea and the level of excretion of *C. parvum* to a greater extent than placebo (a dummy treatment). Another trial of calves aged from 24 to 48 hours also compared Halocur with placebo and showed that medicine was effective at preventing diarrhoea due to *C. parvum*. Early treatment in the first 24 to 48 hours after birth was shown to be most beneficial.



What are the risks associated with Halocur?

Halocur should not be given to calves with diarrhoea present for more than 24 hours, or to weak animals.

For the full list of side effects and restrictions of Halocur, see the package leaflet.

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

People who handle Halocur repeatedly may develop skin allergies. Users should avoid skin and eye contact with the product and if such contact happens, they should wash the exposed area thoroughly with clean water. If eye irritation persists, medical advice should be sought. Protective gloves should be worn while handling the product and hands should be washed after use.

Halocur should not enter watercourses as this may be dangerous for fish and other aquatic organisms. Any unused product or waste materials should be disposed of in accordance with local requirements.

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 Halocur is 13 days.

Why is Halocur authorised in the EU?

The European Medicines Agency decided that Halocur's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Halocur

Halocur received a marketing authorisation valid throughout the EU on 29 October 1999.

Further information on Halocur can be found on the Agency's website:

ema.europa.eu/medicines/veterinary/EPAR/Halocur.

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