EMEA/V/C/054
EMEA/CVMP/417488/2006

EPAR summary for the public

Pirsue

Pirlimycin hydrochloride

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Pirsue?

Pirsue is an antibiotic that contains pirlimycin hydrochloride as the active substance. It is given to dairy cows by infusion into the udder via the teat canal using a pre-filled syringe.

What is Pirsue used for?

Pirsue is used in dairy cows to treat subclinical mastitis caused by specific groups of bacteria. Mastitis is an infection in the udder. Subclinical means that the infection is present but not sufficiently developed to produce clear clinical signs in the cow. Since milk is routinely checked for bacteria and other signs of infection, early stages of an udder infection in a dairy cow can easily be diagnosed. Pirsue is given into each infected teat of the udder for 8 consecutive days.

How does Pirsue work?

The active substance in Pirsue is pirlimycin hydrochloride, an antibiotic of the lincosamide group. It works by blocking the bacteria's ribosomes; this is the part of the cell where proteins are produced. As a result, the bacteria cannot produce any more protein and will stop growing.

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How has Pirsue been studied?

Information was provided on the pharmaceutical quality, the tolerance of the product in cows and the safety in humans (people in contact with the product and consumers of meat and milk) and the environment.

The antimicrobial effectiveness of pirlimycin against different groups of bacteria causing disease in dairy cows was investigated in microbiological laboratories. In these studies, the effective concentration of pirlimycin required to stop bacterial growth was established.

The clinical effectiveness was studied in a large number of dairy herds in 8 European countries. Cows with subclinically infected udders were treated with Pirsue (once daily for 8 days) or with another antibiotic, authorised in the EU to treat these infections. Milk samples were checked daily up to 30 days after treatment for bacteria and for other signs of infection.

What benefit has Pirsue shown during the studies?

The results of these studies showed that Pirsue is effective at inhibiting the bacterial growth of a range of bacteria. The field trial showed that treatment with Pirsue at the recommended dose was effective in the treatment of subclinical udder infections.

What is the risk associated with Pirsue?

Pirsue is generally well tolerated in cows.

However, in rare cases, serious bacterial udder infections have occurred after treatment. These infections were caused by incorrect administration of the product by the operator who, by inserting the syringe without adequate cleansing procedures, also inserted pathogenic (disease causing) bacteria from the environment into the udder. Special care must, therefore, be taken by the operator not to introduce pathogens into the teat. Both, the teat and the udder should be adequately cleansed and the teat end disinfected before using Pirsue.

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

Pirlimycin hydrochloride can cause severe eye and skin irritation.

Care should, therefore, be taken by the user of the product to avoid contact with the solution. Skin that has been in contact with Pirsue should be washed and eyes should be flushed with water for 15 minutes immediately after exposure.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

After the last day of treatment with Pirsue, treated cows should not be slaughtered for 23 days.

What is the time to allow before milk can be taken from the animal for human consumption?

After the last day of treatment with Pirsue, milk from treated cows should not be used for 5 days.

Why has Pirsue been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Pirsue exceed the risks for the treatment of subclinical mastitis in lactating cows and recommended that Pirsue be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Pirsue:

The European Commission granted a marketing authorisation valid throughout the European Union, for Pirsue on 29 January 2001. The authorisation was renewed on 29 January 2006. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in May 2013.