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## **EPAR summary for the public**

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# Novem meloxicam

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 Novem and what is it used for?**

Novem is an anti-inflammatory medicine used in cattle and pigs. It contains the active substance meloxicam.

In cattle, Novem is used to treat:

- acute respiratory infection (infection of the lungs and airways) together with antibiotics
- diarrhoea in calves of over one week of age and young, non-lactating cattle together with oral re-hydration therapy (medicines given by mouth to restore water levels in the body)
- pain following dehorning in calves
- acute mastitis (inflammation of the udder) together with the main treatment with antibiotics.

In pigs, Novem is used to treat:

- lameness and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move)
- pain following minor soft tissue surgery such as castration
- infections that occur after farrowing (giving birth) such as puerperal septicaemia and toxæmia (mastitis-metritis-agalactia syndrome) together with the main treatment with antibiotics.



## **How is Novem used?**

Novem is available as a solution for injection and can only be obtained with a prescription. The dose to use depends on the animal and its bodyweight. Injections are given under the skin for cattle and into the muscles for pigs.

## **How does Novem work?**

Novem contains meloxicam, which 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 Novem have been shown in studies?**

Appropriate studies have been carried out in various target animals to show that Novem is effective and safe in its approved uses. The studies showed that the addition of Novem to antibiotic therapy significantly improved clinical parameters and reduced fever compared to antibiotics alone. Similarly, treatment combining rehydration solution and Novem was shown to be superior to rehydration solution alone.

## **What are the risks associated with Novem?**

In cattle and pigs both subcutaneous and intramuscular administration are well tolerated; only a slight temporary swelling at the injection site following subcutaneous administration was observed in less than 10% of the cattle treated in clinical studies.

In very rare cases anaphylactoid (allergic) reactions which may be serious (including fatal) may occur and should be treated symptomatically.

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

People who are hypersensitive (allergic) to NSAIDs should avoid contact with Novem. If the product is accidentally self-injected, the advice of a doctor should be sought immediately.

## **What is the withdrawal period in food-producing animals?**

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat or milk used for human consumption.

### Cattle

The withdrawal period is 15 days for meat and five days for milk.

### Pigs

The withdrawal period for meat is five days.

## **Why is Novem approved?**

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

## **Other information about Novem:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Novem on 2 March 2004. The full EPAR for Novem can be found on the Agency's website: [ema.europa.eu/Find medicine/Veterinary Medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Veterinary%20Medicines/European%20public%20assessment%20reports). For more information about treatment with Novem, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2017.