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EPAR summary for the public

Recuvyra

fentanyl

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 Recuvyra?

Recuvyra is a medicine that contains the active substance fentanyl. It is available as a transdermal solution (a solution applied to the skin).

What is Recuvyra used for?

Recuvyra is used to control pain in dogs that have undergone major orthopaedic (bone) or soft tissue surgery. It is given by a veterinarian.

The recommended dose is 2.6 mg per kilogram bodyweight applied with a specially designed syringe to the skin between the shoulder blades of the dog. It is given once only, two to four hours before surgery, and its effects will last for at least four days.

How does Recuvyra work?

The active substance in Recuvyra, fentanyl, is an opioid painkiller. When applied to the skin of dogs, a dose of fentanyl is rapidly absorbed into the blood stream through the blood vessels below the skin. Once in the bloodstream, fentanyl acts on receptors in the brain and spinal cord to relieve pain.

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How has Recuvyra been studied?

In two main studies, dogs undergoing orthopaedic or soft tissue surgery were either given Recuvyra or buprenorphine (another opioid painkiller) in advance of surgery to control their pain. The studies compared the two medicines in terms of failure rate (dogs that had to be taken off treatment due to lack of pain control) and the need for additional treatment to counteract the harmful effects of opioid medicines.

What benefit has Recuvyra shown during the studies?

In both studies Recuvyra was as effective as the comparator medicine in treating pain in dogs following orthopaedic or soft tissue surgery.

What is the risk associated with Recuvyra?

Recuvyra very commonly causes sleepiness which may last for more than 24 hours after applying the medicine, and which can be associated with reduced food and water intake, decreased stool production and transient weight loss. Other side effects include mild reductions in body temperature, heart rate and breathing rate for up to three days following use. Diarrhoea and vomiting are also common side effects.

Recuvyra must not be use in dogs that are allergic to the active substance or any other ingredient. Recuvyra must not be used on skin that is broken or damaged due to injury or disease. For the full list of restrictions, see the package leaflet.

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

The person administering Recuvyra should avoid contact with their skin as the medicine can be absorbed by human skin and may cause reactions in people, including skin irritation. If symptoms develop as a result of exposure to Recuvyra, medical advice should be sought immediately. The most common symptoms associated with fentanyl overdose in people include respiratory depression, sleepiness and myosis (narrowing of the pupil in the eye).Protective equipment of clothing should be used when handling the medicine.

Contact with the dog's skin after application of Recuvyra should not cause problems for adults. However, small children (15kg or less) should not touch the dog for three days after the medicine has been applied, as they may be exposed to a large amount of fentanyl.

Why has Recuvyra been approved?

Recuvyra was shown to be as effective as the comparator medicines with the added advantage of being easy to apply. The CVMP decided that the benefits of Recuvyra outweighed its risks and recommended that it be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Recuvyra:

The European Commission granted a marketing authorisation valid throughout the European Union, for Recuvyra on 6 October 2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in February 2012.