EPAR summary for the public

Fevaxyn Pentofel

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 Fevaxyn Pentofel?

Fevaxyn Pentofel is a vaccine for cats which is a solution for injection in a prefilled syringe. Fevaxyn Pentofel contains the following inactivated viruses: feline panleukopenia virus, feline rhinotracheitis virus, feline calicivirus, feline leukaemia virus, and the inactivated bacterium feline Chlamydophila felis.

What is Fevaxyn Pentofel used for?

Fevaxyn Pentofel is used to immunise healthy cats of 9 weeks or older against feline panleukopenia and feline leukaemia and against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and feline Chlamydophila felis.

The contents of the prefilled syringe are shaken and given by subcutaneous (under the skin) injection. For cats 9 weeks and older, two doses are given at an interval of 3 to 4 weeks. An additional dose is recommended for kittens living in high-risk areas for feline leukaemia virus whose first dose was administered before 12 weeks of age. Fevaxyn Pentofel is then given once every year.
How does Fevaxyn Pentofel work?

Fevaxyn Pentofel contains small amounts of four inactivated viruses and one inactivated bacterium. When injected, this small exposure helps the cat’s immune system to recognise and attack the viruses and bacterium. When exposed to any of these viruses and bacterium later in life, the cat will either not become infected or will have a much less serious infection.

How has the effectiveness of Fevaxyn Pentofel been studied?

Fevaxyn Pentofel has been studied against Feline Leukaemia, against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and feline *Chlamydophila felis*, as well as against disease caused by feline panleukopenia virus.

In addition, studies in cats of various breeds were carried out to observe any side effects of Fevaxyn Pentofel after the first and second vaccinations.

What benefit has Fevaxyn Pentofel shown during the studies?

Fevaxyn Pentofel has been shown to be effective against Feline Leukaemia, against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and feline *Chlamydophila felis*, as well as against disease caused by feline panleukopenia virus.

In the trial to observe side effects, there were no side effects in 94.2% of cats for the first vaccination and no side effects observed for 99% of cats for the second vaccination.

What are the side effects of Fevaxyn Pentofel?

Some vaccinated cats may develop reactions to the vaccine, which include temporary fever, vomiting, anorexia (not eating), and/or depression, which usually disappear within 24 hours.

Occasionally there is swelling, pain, pruritus (itching) or hair loss at the injection site. In very rare cases there is an anaphylactic reaction (severe allergy) with oedema (fluid under the skin), pruritus, respiratory and cardiac distress, severe gastrointestinal signs or shock during the first hours after vaccination.

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

Fevaxyn Pentofel contains mineral oil. Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger – rarely causing the loss of a finger. If someone is accidentally injected with this product, they must seek immediate medical advice even if only a very small amount is injected. The Package Leaflet should be taken to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

Why has Fevaxyn Pentofel been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Fevaxyn Pentofel are greater than any risks to immunise healthy cats of 9 weeks or older against feline viruses. They recommended that Fevaxyn Pentofel should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion of this EPAR.
Other information about Fevaxyn Pentofel:

The European Commission granted a marketing authorisation valid throughout the European Union, for Fevaxyn Pentofel on 5 February 1997. Information on the prescription status of this product may be found on the outer package.

This summary was last updated in June 2013.