

EMA/171616/2017
EMA/V/C/004645

EPAR summary for the public

Ingelvac PCV Flex

porcine circovirus type 2 vaccine

This is a summary of the European public assessment report (EPAR) for Ingelvac PCV Flex. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Ingelvac PCV Flex.

For practical information about using Ingelvac PCV Flex, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Ingelvac PCV Flex and what is it used for?

Ingelvac PCV Flex is a vaccine used to protect pigs from two weeks of age against porcine circovirus type 2 (PCV2). Ingelvac PCV Flex is to be used in pigs which have no maternally derived antibodies (a special type of proteins, received from the mother in the milk that help the body to fight infection) to PCV2. PCV2 infections can produce clinical signs such as weight loss or failure to grow, enlarged lymph nodes, difficulty breathing, pale skin and jaundice (yellowing of the skin). Ingelvac PCV Flex contains the active substance porcine circovirus type 2 ORF2 protein.

This medicine is the same as Ingelvac CircoFLEX, which is already authorised in the European Union (EU). The company that makes Ingelvac CircoFLEX has agreed that its scientific data can be used for Ingelvac PCV Flex ('informed consent').

How is Ingelvac PCV Flex used?

Ingelvac PCV Flex is available as a suspension for injection and can only be obtained with a prescription. It is given by injection into the muscle as a single dose. The vaccine starts to be effective 2 weeks after vaccination and protection lasts for 17 weeks.

For further information, see the package leaflet.

How does Ingelvac PCV Flex work?

Ingelvac PCV Flex is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Ingelvac PCV Flex contains small amounts of a protein from PCV2. When a pig is given the vaccine, the pig's immune system recognises the protein as 'foreign' and reacts by building up an active immune response. In the future, the immune system will be able to react against the virus more quickly when it is exposed to the virus. This active immune response will help to protect the pig against the disease caused by this virus.

What benefits of Ingelvac PCV Flex have been shown in studies?

Ingelvac PCV Flex has been studied in a number of trials involving pigs of various breeds. These studies were performed under laboratory as well as under typical European farming conditions. The trials showed that vaccination of pigs (which had no antibodies to PCV2 before vaccination) with Ingelvac PCV Flex reduced the levels of PCV2 in the blood, clinical signs of PCV2 infection, virus excreted from the nose and death rates.

What are the risks associated with Ingelvac PCV Flex?

The most common side effect with Ingelvac PCV Flex (which may affect more than 1 in 10 animals) is a mild and short lived increase in body temperature on the day of vaccination.

For the full list of restrictions and all side effects reported with Ingelvac PCV Flex, see the package leaflet.

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

No special precautions are required.

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 pigs treated with Ingelvac PCV Flex is 'zero days', which means there is no mandatory waiting time.

Why is Ingelvac PCV Flex approved?

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

Other information about Ingelvac PCV Flex:

The European Commission granted a marketing authorisation valid throughout the EU for Ingelvac PCV Flex on 24 May 2017.

The full EPAR for Ingelvac PCV Flex can be found on the Agency's website: ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports. For more information about treatment with Ingelvac PCV Flex, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2017.