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## EPAR summary for the public

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# Ingelvac CircoFLEX

## porcine circovirus type 2 vaccine

This is a summary of the European public assessment report (EPAR) for Ingelvac CircoFLEX. 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 CircoFLEX.

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

### What is Ingelvac CircoFLEX and what is it used for?

Ingelvac CircoFLEX is a vaccine used to protect pigs from the two weeks of age against porcine circovirus type 2 (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 CircoFLEX contains the active substance porcine circovirus type 2 ORF2 protein.

### How is Ingelvac CircoFLEX used?

Ingelvac CircoFLEX 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 CircoFLEX work?

Ingelvac CircoFLEX is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Ingelvac CircoFLEX 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 CircoFLEX have been shown in studies?**

Ingelvac CircoFLEX 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 with Ingelvac CircoFLEX reduced weight loss in the piglets. It also reduced the levels of PCV2 in the blood, clinical signs of PCV2 infection, the number of runts and death rates.

### **What are the risks associated with Ingelvac CircoFLEX?**

The most common side effect with Ingelvac CircoFLEX (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 CircoFLEX, 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 CircoFLEX is 'zero days', which means there is no mandatory waiting time.

### **Why is Ingelvac CircoFLEX approved?**

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

### **Other information about Ingelvac CircoFLEX:**

The European Commission granted a marketing authorisation valid throughout the EU for Ingelvac CircoFLEX on 13 February 2008.

The full EPAR for Ingelvac CircoFLEX can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Veterinary\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports). For more information about treatment with Ingelvac CircoFLEX, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2017.