



## EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

### GRIPOVAC 3

#### EPAR summary for the public

*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 Gripovac 3?

Gripovac 3 is a vaccine that contains 3 different strains of swine influenza A virus which have been inactivated (killed). Gripovac 3 is a suspension for injection.

#### What is Gripovac 3 used for?

Gripovac 3 is used to vaccinate pigs including pregnant sows over the age of 56 days against swine influenza in order to help them clinically but also to reduce the amount of virus present in the lungs. Gripovac 3 is also used to vaccinate pregnant sows following their first immunisation by giving them one dose 14 days prior to farrowing in order that the sows milk contains enough antibodies to help protect the piglets against swine influenza for at least 33 days after birth.

#### How does Gripovac 3 work?

Gripovac 3 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Gripovac 3 contains small amounts of a modified and then killed form of the pig's influenza virus that causes lesions and illness. The vaccine also contains 'adjuvants' to stimulate a better response. When a pig is given the vaccine, the immune system recognises the killed viruses as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is again exposed to the viruses. This protects the pigs against the disease.

#### How has Gripovac 3 been studied?

The effectiveness of Gripovac 3 has been studied in animals 56 days of age and older and in sows before and during pregnancy and these studies document that the vaccine protects against swine influenza.

#### What benefit has Gripovac 3 shown during the studies?

Use of the Gripovac 3 in pigs reduces clinical signs and reduces the amount of virus in the lungs after infection caused by swine influenza A virus.

**What is the risk associated with Gripovac 3?**

A slight swelling may occur after vaccination at the site of injection in a small number of pigs but this goes down within 2 days. Sometimes, a slight increase in the rectal temperature might occur after vaccination.

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

In case of accidental self-injection only a minor injection site reaction is expected.

**What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?**

Zero days

**Why has Gripovac 3 been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Gripovac 3 exceed the risks for the vaccination of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection and recommended that Gripovac 3 be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

**Other information about Gripovac 3:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Gripovac 3 to Merial on 14.01.2010. Information on the prescription status of this product may be found on the label/outer package.

**This summary was last updated on 14.01.2010.**

Medicinal product no longer authorised