



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/188700/2017
EMA/V/C/003993

Resporc FLUpan H1N1 (*porcine influenza vaccine (inactivated)*)

An overview of Resporc FLUpan H1N1 and why it is authorised in the EU

What is Resporc FLUpan H1N1 and what is it used for?

Resporc FLUpan H1N1 is a vaccine used to protect pigs from eight weeks of age against swine influenza caused by pandemic subtype H1N1. Swine influenza or swine flu is a disease of the lungs and airways in pigs. Signs can include fever, depression, coughing, sneezing, difficulty breathing and loss of appetite. The vaccine can also be used during pregnancy up to three weeks before expected farrowing and during lactation.

The vaccine contains inactivated (killed) influenza A virus/Jena/VI5258/2009(H1N1)pdm09, a strain of the virus that causes swine influenza.

How is Resporc FLUpan H1N1 used?

Resporc FLUpan H1N1 is available as a suspension for injection and can only be obtained with a prescription. It is given as two injections into the muscle, three weeks apart. The vaccine starts to be effective one week after the second injection and protection lasts for three months.

For more information about using Resporc FLUpan H1N1, see the package leaflet or contact your veterinarian or pharmacist.

How does Resporc FLUpan H1N1 work?

Resporc FLUpan H1N1 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Resporc FLUpan H1N1 contains influenza A virus (Pan H1N1) which has been inactivated so it cannot cause the disease. When a pig is given the vaccine, the pig's immune system recognises the virus 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.

Resporc FLUpan H1N1 contains an adjuvant (carbomer) to enhance the immune response.

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What benefits of Respiporc FLUpan H1N1 have been shown in studies?

The effectiveness of Respiporc FLUpan H1N1 in pigs from eight weeks of age was shown in three laboratory studies and one combined field/laboratory study. The studies showed that pigs vaccinated with Respiporc FLUpan H1N1 had a reduction in the amount of virus in the lung and excreted from the nose. Two laboratory studies and a field study showed that vaccination during pregnancy and lactation was well-tolerated and no negative effects on reproduction were seen.

What are the risks associated with Respiporc FLUpan H1N1?

The most common side effects with Respiporc FLUpan H1N1 (which may affect up to 1 in 10 animals) are a short-lived increase in rectal temperature, not exceeding 2°C, which does not last for more than one day and a transient swelling up to 2 cm³ at the site of injection which usually resolves within 5 days.

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

No special precautions are required. In case of accidental self-injection, only a minor injection site reaction is expected.

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 vaccinated with Respiporc FLUpan H1N1 is 'zero' days, which means that there is no mandatory waiting time.

Why is Respiporc FLUpan H1N1 authorised in the EU?

The European Medicines Agency decided that Respiporc FLUpan H1N1's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Respiporc FLUpan H1N1

Respiporc FLUpan H1N1 received a marketing authorisation valid throughout the EU on 17 May 2017.

Further information on Respiporc FLUpan H1N1 can be found on the Agency's website:

ema.europa.eu/medicines/veterinary/EPAR/respiporc-flupan-h1n1.

This overview was last updated in 11-2021.