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EPAR summary for the public

Resporc FLUpa H1N1

Porcine influenza vaccine (inactivated)

This is a summary of the European public assessment report (EPAR) for Resporc FLUpa H1N1. 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 Resporc FLUpa H1N1.

For practical information about using Resporc FLUpa H1N1, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

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

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

How is Resporc FLUpa H1N1 used?

Resporc FLUpa 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 further information, see the package leaflet.

How does Resporc FLUpa H1N1 work?

Resporc FLUpa H1N1 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Resporc FLUpa 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.

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

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

The effectiveness of Respiporc FLUpan H1N1 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 of virus in the lung and excreted from the nose.

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

Why is Respiporc FLUpan H1N1 approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Respiporc FLUpan H1N1's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Respiporc FLUpan H1N1:

The European Commission granted a marketing authorisation valid throughout the EU for Respiporc FLUpan H1N1 on 17 May 2017.

The full EPAR for Respiporc FLUpan H1N1 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 Respiporc FLUpan H1N1, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2017.