SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1 suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Inactivated influenza A virus/human
Strain: A/Jena/VI5258/2009(H1N1)pdm09 ≥ 16 HU[1]

[1] HU – haemagglutinating units.

Adjuvant:
Carbomer 971P NF 2 mg

Excipient:
Thiomersal 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Clear to slightly turbid, reddish to pale-pink coloured suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Active immunisation of pigs from the age of 8 weeks onwards against pandemic H1N1 porcine influenza virus to reduce viral lung load and viral excretion.

Onset of immunity: 7 days after primary vaccination.
Duration of immunity: 3 months after primary vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

i) Special precautions for use in animals

Not applicable.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in rectal temperature, not exceeding 2 °C, is common after vaccination and this does not persist for more than one day.
A transient swelling up to 2 cm^3 may occur at the site of injection: these reactions are common but resolve within 5 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amount(s) to be administered and administration route

For intramuscular use.

Vaccination: 2 injections of one dose (1 ml) from the age of 56 days, with an interval of 3 weeks between injections.

The efficacy of revaccination has not been investigated and therefore no revaccination schedule is proposed.

Maternally-derived antibodies in piglets interfere with the RESPIPORC FLUpan H1N1 mediated immunity. Generally, maternally-derived antibodies induced by vaccination last for approximately 5–8 weeks after birth.

In cases of exposure of the sows to antigens (from either field infections and/or vaccination) the antibodies transmitted to the piglets can interfere with active immunisation at 12 weeks of age. In such cases the piglets should be vaccinated after the age of 12 weeks.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, inactivated viral vaccines for pigs, porcine influenza virus.

ATC Vet Code: QI09AA03.

The vaccine stimulates an active immunity against pandemic porcine influenza A/Jena/VI5258/2009 (H1N1)pandemic09-like virus. It induces neutralising and haemagglutination-inhibiting antibodies against this subtype. The antibody responses mentioned in the following have been documented in pigs without maternally-derived immunity. Neutralising antibodies in serum have been detected in more than 75% of the immunised pigs on day 7 after primary immunisation lasting in more than 75% of the pigs for over 3 months. Haemagglutination-inhibiting antibodies have been detected in 15–100% of the immunised pigs on day 7 after primary immunisation which disappeared in the majority of animals within 1 to 4 weeks thereafter.

Efficacy of the vaccine was examined in laboratory challenge studies in pigs without maternally-derived antibodies and was demonstrated against the following strains:
FLUAV/Hamburg/NY1580/2009(H1N1)pdm09 (human origin),
FLUAV/swine/Schallern/IDT19989/2014 (H1N1)pdm09 (swine origin) and
FLUAV/sw/Teo(Spain)/AR641/2016 (H1N1)pdm09 (swine origin).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 971P NF
Thiomersal
Sodium chloride solution (0.9%)

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the vial: 10 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 ºC−8 ºC). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

PET vials:	25 ml polyethylene terephthalate (PET) vials 50 ml PET vials
Stoppers:	Bromobutyl rubber stoppers
Caps:	Aluminium flanged caps

Package sizes:
Cardboard box with 1 vial of 25 doses (25 ml) or 50 doses (50 ml) with a rubber stopper and flanged cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
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8. MARKETING AUTHORISATION NUMBER

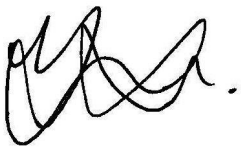
Vm 15052/5017

9. DATE OF FIRST AUTHORISATION

16 May 2017

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 20 October 2022