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 Indication 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

Special precautions for use in animals

Not applicable.

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.

Special precautions for the protection of the environment

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1] Hyperthermia[2].

[1] transient swelling up to 2 cm^3, resolves within 5 days.
[2] transient increase in rectal temperature not exceeding 2°C, does not persist for more than one day.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy up to three weeks before expected farrowing and during 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 Amounts to be administered and administration route

For intramuscular use.

Piglets:
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.

Gilts and sows:
Primary vaccination: 2 injections of one dose (1 ml) with an interval of 3 weeks between injections and up to 3 weeks before expected farrowing or during lactation.

The efficacy of single dose revaccination has not been investigated and therefore no single dose revaccination schedule is proposed for further pregnancies.

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.
ATCvet 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 immediate packaging: 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
LDPE bottles:	50 ml low density polyethylene (LDPE) bottles
Glass vials:	25 ml glass vials, glass type I
Stoppers:	Bromobutyl rubber stoppers
Caps:	Aluminium flanged caps

Package sizes:
Cardboard box with 1 PET vial of 25 doses (25 ml) or 50 doses (50 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 LDPE bottle of 25 doses (25 ml) or 50 doses (50 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 glass vial of 25 doses (25 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 products or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5017

9. DATE OF FIRST AUTHORISATION

16 May 2017

10. DATE OF REVISION OF THE TEXT

June 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall

Approved 11 January 2025