ANNEX I

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Sodium chloride solution (0.9%)	

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each 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: 1 week ~~7 days~~ after primary vaccination.
Duration of immunity: 3 months after primary vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

3.6 Adverse events

Target species: pigs.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy up to three weeks before expected farrowing and during lactation.

3.8 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.

3.9 Administration routes and dosage

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 revaccinations 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AA03.

Immunologicals, inactivated viral vaccines for pigs, porcine influenza virus.

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/209/001–005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 17/05/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 25 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:
Inactivated influenza A virus/human
Strain: A/Jena/VI5258/2009(H1N1)pdm09 ≥ 16 HU[1]

[1] HU – haemagglutinating units.

3. PACKAGE SIZE

25 ml (25 doses)
50 ml (50 doses)

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/209/001 (25 doses PET bottle)
EU/2/17/209/002 (50 doses PET bottle)
EU/2/17/209/003 (25 doses glass vial)
EU/2/17/209/004 (25 doses LDPE bottle)
EU/2/17/209/005 (50 doses LDPE bottle)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated influenza A virus/human, strain A/Jena/VI5258/2009(H1N1)pdm09: ≥ 16 HU

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

IM

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

9. BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated influenza A virus/human, strain A/Jena/VI5258/2009(H1N1)pdm09: ≥ 16 HU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

RESPIPORC FLUpan H1N1 suspension for injection for pigs

2. 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

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

3. Target species

Pigs

4. Indications for use

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

Onset of immunity: 1 week after primary vaccination.
Duration of immunity: 3 months after primary vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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.

Pregnancy and lactation:
Can be used during pregnancy up to three weeks before expected farrowing and during lactation.

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.

Overdose:
None known.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Target species: pigs.

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

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 revaccinations 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.

9. Advice on correct administration

None.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of the month.

Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/209/001–005

Package sizes:

Cardboard box with 1 polyethylene terephthalate (PET) vial of 25 doses (25 ml) or 50 doses (50 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 low density polyethylene (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.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France
Telephone number: 00 800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

17. Other information

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).