ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Strains of inactivated Influenza A virus/swine/

Bakum/IDT1769/2003 (H3N2)	≥ 10.53 $\log_2$ GMNU[1]
Haselünne/IDT2617/2003 (H1N1)	≥ 10.22 $\log_2$ GMNU[1]
Bakum/1832/2000 (H1N2)	≥ 12.34 $\log_2$ GMNU[1]

[1]GMNU = Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine

Adjuvant:
Carbomer 971P NF 2.0 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	0.21 mg
Sodium chloride solution (0.9%)	

Clear, yellowish orange to pink coloured suspension for injection.

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 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

Onset of immunity: 1 week after primary vaccination
Duration of immunity: 4 months in pigs vaccinated between the age of 56 and 96 days and
6 months in pigs vaccinated for the first time at 96 days and above.

Active immunisation of pregnant sows after finished primary immunisation by administration of a single dose 14 days prior to farrowing to develop high colostral immunity which provides clinical protection of piglets for at least 33 days after birth.

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. In case of accidental self-injection only a minor injection site reaction is expected.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: pig.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1,2] Elevated temperature[2]

[1] Regressing within 2 days
[2] Transient

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

Pregnancy and lactation:

Can be used during pregnancy and 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:
Primary vaccination: 2 injections of one dose (2 ml)
- From the age of 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 6 months.
or
- Between the age of 56 and 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 4 months.

Gilts and sows:
Primary vaccination: see above
A booster is possible at each stage of pregnancy and lactation. When vaccination is performed 14 days prior to farrowing with one dose (2 ml), it provides maternally-derived immunity to the piglets which protects them from clinical signs of influenza at least until day 33 after birth.

Maternally-derived immunity in the piglets interacts with antibody induction. Generally, maternally-derived antibodies induced by vaccination last for approx. 5-8 weeks after birth. In particular cases of multiple contacts of the sows with antigens (field infections + vaccination) the antibodies transmitted to the piglets may last until week 12 of life. In the latter case piglets should be vaccinated after the age of 96 days.

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

After administration of a double dose (4 ml), no adverse reactions other than those described in section 3.6 were observed.

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.

The vaccine stimulates an active immunity against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2. It induces neutralizing and haemagglutination inhibiting antibodies against each of the three subtypes. When a single dose of the vaccine is administered 14 days prior to farrowing as a booster to previously vaccinated sows, the vaccine stimulates active immunity in order to provide maternally-derived immunity to the progeny against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2.

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 immediate packaging: 10 hours.

5.3 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.

5.4 Nature and composition of immediate packaging

Glass vial:	25 ml vials, glass type I 50 ml vials, glass type II 100 ml vials, glass type II
PET vials:	20 ml Polyethylene terephthalate (PET) vials, clear 50 ml PET vials, clear 100 ml PET vials, clear 500 ml PET vials, clear
LDPE bottles:	50 ml Low Density Polyethylene (LDPE) bottles 100 ml LDPE bottles
Stoppers:	Bromobutyl rubber stoppers
Caps:	Flanged caps

Package sizes:
Cardboard box with 1 glass vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 PET vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.
Cardboard box with 8 PET vials of 250 doses (500 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 LDPE bottle of 25 doses (50 ml) or 50 doses (100 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/2/09/103/001-009

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 14/01/2010

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

{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 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses), 8 x 500 ml (8 x 250 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Strains of inactivated Influenza A virus/swine/
Bakum/IDT1769/2003 (H3N2) ≥ 10.53 $\log_2$ GMNU
Haselünne/IDT2617/2003(H1N1) ≥ 10.22 $\log_2$ GMNU
Bakum/1832/2000 (H1N2) ≥ 12.34 $\log_2$ GMNU

3. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
8 x 500 ml (250 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. Keep the vial in the outer carton in order to 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/2/09/103/001 (10 doses glass vial)
EU/2/09/103/002 (25 doses glass vial)
EU/2/09/103/003 (50 doses glass vial)
EU/2/09/103/004 (10 doses PET vial)
EU/2/09/103/005 (25 doses PET vial)
EU/2/09/103/006 (50 doses PET vial)
EU/2/09/103/007 (250 doses PET vial)
EU/2/09/103/008 (25 doses LDPE bottle)
EU/2/09/103/009 (50 doses LDPE bottle)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 50 ml (25 doses), 100 ml (50 doses) and 500 ml (250 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Strains of inactivated Influenza A virus/swine/
Bakum/IDT1769/2003 (H3N2) ≥ 10.53 $\log_2$ GMNU
Haselünne/IDT2617/2003 (H1N1) ≥ 10.22 $\log_2$ GMNU
Bakum/1832/2000 (H1N2) ≥ 12.34 $\log_2$ GMNU

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

IM
Read the package leaflet before use.

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. Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 ml (10 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Strains of inactivated Influenza A virus/swine
H3N2 ≥ 10.53 log_2 GMNU, H1N1 ≥ 10.22 log_2 GMNU, H1N2 ≥ 12.34 log_2 GMNU

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 FLU3 suspension for injection for pigs

2. Composition

Each dose of 2 ml contains:

Active substances:

Strains of inactivated Influenza A virus/swine/	
Bakum/IDT1769/2003 (H3N2)	≥ 10.53 $\log_2$ GMNU[1]
Haselünne/IDT2617/2003 (H1N1)	≥ 10.22 $\log_2$ GMNU[1]
Bakum/1832/2000 (H1N2)	≥ 12.34 $\log_2$ GMNU[1]

[1]GMNU = Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine

Adjuvant:

Carbomer 971P NF	2.0 mg

Excipient:

Thiomersal	0.21 mg

Clear, yellowish orange to pink coloured suspension for injection.

3. Target species

Pigs

4. Indications for use

Active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

Onset of immunity:	1 week after primary vaccination
Duration of immunity:	4 months in pigs vaccinated between the age of 56 and 96 days and 6 months in pigs vaccinated for the first time at 96 days and above.

Active immunisation of pregnant sows after finished primary immunisation by administration of a single dose 14 days prior to farrowing to develop high colostral immunity which provides clinical protection of piglets for at least 33 days after birth.

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. In case of accidental self-injection only a minor injection site reaction is expected.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Can be used during pregnancy and 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:
After administration of a double dose (4 ml), no adverse reactions other than those described in section 7 were observed.

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

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

7. Adverse events

Target species: pig.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1,2] Elevated temperature[2]

[1] Regressing within 2 days
[2] Transient

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:
Primary vaccination: 2 injections of one dose (2 ml)
- From the age of 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 6 months.
or
- Between the age of 56 and 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 4 months.

Gilts and sows:
Primary vaccination: see above
A booster is possible at each stage of pregnancy and lactation. When vaccination is performed 14 days prior to farrowing with one dose (2 ml), it provides maternally-derived immunity to the piglets which protects them from clinical signs of influenza at least until day 33 after birth.

Maternally-derived immunity in the piglets interacts with antibody induction. Generally, maternally-derived antibodies induced by vaccination last for approx. 5-8 weeks after birth. In particular cases of multiple contacts of the sows with antigens (field infections + vaccination) the antibodies transmitted to the piglets may last until week 12 of life. In the latter case piglets should be vaccinated after the age of 96 days.

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 ºC − 8 ºC).
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 that 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/2/09/103/001-009

Package sizes:
Cardboard box with 1 glass or PET vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.
Cardboard box with 8 PET vials of 250 doses (500 ml) with a rubber stopper and flanged cap.
Cardboard box with 1 LDPE bottle of 25 doses (50 ml) or 50 doses (100 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

{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
8 rue de logrono33500 Libourne
France
Tel: 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 Swine Influenza A virus subtypes H1N1, H3N2 and H1N2. It induces neutralizing and haemagglutination inhibiting antibodies against each of the three subtypes. When a single dose of the vaccine is administered 14 days prior to farrowing as a booster to previously vaccinated sows, the vaccine stimulates active immunity in order to provide maternally-derived immunity to the progeny against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2.