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).