

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Cardboard box for 20 ml,
50 ml, 100 ml, 8 x 500 ml**

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)

500 ml (250 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 Animal Health Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5016

15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - Vial of 50 ml, 100 ml
and 500 ml**

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 periods: 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 Animal Health Ltd

9. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS -
Vial of 20 ml**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Respiporc FLU3

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 10 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Resporc 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) $\geq 10.53 \log_2$ GMNU¹

Haselünne/IDT2617/2003 (H1N1) $\geq 10.22 \log_2$ GMNU¹

Bakum/1832/2000 (H1N2) $\geq 12.34 \log_2$ GMNU¹

¹GMNU = 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: pigs.

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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 °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 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

Vm 15052/5016

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

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

POM-V ('Veterinary medicinal product subject to prescription')

For animal treatment only.

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

Revised: February 2025
AN: 00357/2024

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.

Gavin Hall

Approved: 20 February 2025