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 for pigs

2. STATEMENT OF ACTIVE AND OTHER 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. INDICATION(S)

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 Animal Health Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5017

15. BATCH NUMBER

Lot:

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 25 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1 suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot:

4. EXPIRY DATE

EXP {mm/yyyy}
Once opened, use within 10 hours.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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: 7 days 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.

Other precautions
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.

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

7. ADVERSE EVENTS

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:

E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTE 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 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 their active vaccination at 12 weeks of age. In such cases the piglets should therefore 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 PERIOD(S)

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.
Shelf life after first opening the container: 10 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

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

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5017

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.

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 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).

Gavin Hall

Approved 11 January 2025