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 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. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5017

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:
RESPIPORC FLUpan H1N1 suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1 suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each dose of 1 ml contains:

Active substance:
Inactivated Influenza A virus/human
Strain: A/Jena/VI5258/2009(H1N1) pdm09 $\geq$ 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.

4. INDICATION(S)

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. ADVERSE REACTIONS

A transient increase in rectal temperature, not exceeding 2 °C, is common after vaccination and this does not persist for more than one day.
A transient swelling up to 2 cm^3 may occur at the site of injection, these reactions are common but resolve within 5 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular use.

Vaccination: 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.

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 vial: 10 hours.

12. SPECIAL WARNING(S)

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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established 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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

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

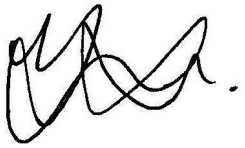
15. OTHER INFORMATION

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).

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.

Not all pack sizes may be marketed.



Vm 15052/5017 Approved: 20 October 2022