

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpa H1N1 suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:

Inactivated influenza A virus/human

Strain: A/Jena/VI5258/2009(H1N1)pdm09 16–64 HU¹

¹ HU – haemagglutinating units in the vaccine.

Adjuvant:

Carbomer 971 P NF 2 mg

Excipient:

Thiomersal 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Clear to slightly turbid, reddish to pale-pink coloured suspension.

4. CLINICAL PARTICULARS

4.1. Target species

Pigs.

4.2. Indication for use, specifying the target species

Active immunisation of pigs from the age of 8 weeks onwards against pandemic H1N1 porcine influenza virus to reduce viral lung load and viral excretion.

Onset of immunity: 7 days after primary vaccination.

Duration of immunity: 3 months after primary vaccination.

4.3. Contraindications

None.

4.4. Special warnings for each target species

Vaccinate healthy animals only.

4.5. Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

4.6. Adverse reactions (frequency and seriousness)

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 cm³ 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).

4.7. Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

4.8. 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.

4.9. Amounts to be administered and administration route

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 FLUp^{an} H1N1 mediated immunity. Generally, maternally-derived antibodies induced by vaccination last for approximately 5-8 weeks after birth.

In case of exposure of sows with antigens (field infections and/or vaccination) the antibodies transmitted to the piglets can interfere with active vaccination at 12 weeks of age. In this case piglets should be vaccinated after the age of 12 weeks.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11. Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, inactivated viral vaccines for pigs, porcine influenza virus.

ATCvet code: QI09AA03.

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. Hemagglutination-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).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carbomer 971 P NF

Thiomersal

Sodium chloride solution (0.9%)

6.2. Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

Shelf life after first opening the bottle: 10 hours.

6.4. Special precautions for storage

Store in a refrigerator (2 °C–8 °C). Do not freeze.

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

6.5. Nature and composition of immediate packaging

PET bottles: 25 ml polyethylene terephthalate (PET) bottles
50 ml PET bottles

Stoppers: Bromobutyl rubber stoppers

Caps: Aluminium flanged caps

Package sizes:

Cardboard box with 1 bottle of 25 doses (25 ml) or 50 doses (50 ml) with a rubber stopper and flanged cap.

Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/209/001–002

9. DATE OF FIRST AUTHORISATION

Date of first authorisation: 17/05/2017

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
GERMANY

Name and address of the manufacturer responsible for batch release

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 16–64 HU¹

¹ HU – haemagglutinating units in the vaccine.

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. Keep the bottle in the outer carton in order to 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. To be supplied only on veterinary prescription.

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

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/209/001 (25 doses)

EU/2/17/209/002 (50 doses)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle 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: 16–64 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

Lot:

7. EXPIRY DATE

EXP {month/year}

Once opened, use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

**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 and manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIPORC FLUpan H1N1 suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each dose of 1 ml contains:

Active substance:

Inactivated Influenza A virus/human

Strain: A/Jena/VI5258/2009(H1N1)pdm09 16–64 HU¹

¹ HU – haemagglutinating units in the vaccine.

Adjuvant:

Carbomer 971 P 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 8 weeks 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 cm³ 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 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 case of exposure of sows with antigens (field infections and/or vaccination) the antibodies transmitted to the piglets can interfere with active vaccination at 12 weeks of age. In this case piglets should be vaccinated after the age of 12 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

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.

Shelf life after first opening the bottle: 10 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP.

12. SPECIAL WARNINGS

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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

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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

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. Hemagglutination 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.

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