ANNEX III

LABELLING AND PACKAGE INSERT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX
(1 X 10 DOSES, 1 X 50 DOSES, 1 X 100 DOSES, 10 X 10 DOSES, 10 X 50 DOSES AND 10 X 100 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Aujeszky 783 + O/W, lyophilisate and solvent for emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Live attenuated Aujeszky's disease virus, strain NIA_3-783: $\geq 10^{5.2}$ $CCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for emulsion for injection

4. PACKAGE SIZE

1 x 10 doses (20 ml)
1 x 50 doses (100 ml)
1 x 100 doses (200 ml)

10 x 10 doses (20 ml)
10 x 50 doses (100 ml)
10 x 100 doses (200 ml)

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(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 1 hour.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.

12. SPECIAL 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Zoetis UK Limited

1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5071

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIALS FOR LYOPHILISATE (10, 50 OR 100 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Aujeszky 783 + O/W, lyophilisate for emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live attenuated Aujeszky's disease virus $\geq 10^{5.2}$ $CCID_{50}$

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

10 doses
50 doses
100 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 1 hour.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS VIALS FOR SOLVENT (100 OR 200 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Aujeszky 783 + O/W, solvent for emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

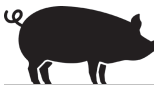
Solvent for emulsion for injection

4. PACKAGE SIZE

100 ml
200 ml

5. TARGET SPECIES

Pigs



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 1 hour.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.

12. SPECIAL 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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5071

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIALS FOR SOLVENT (20 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Aujeszky 783 + O/W, solvent for emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 1 hour.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Suvaxyn Aujeszky 783 + O/W, lyophilisate and solvent for emulsion 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:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:

Zoetis Manufacturing & Research Spain, S.L.
Ctra. de Camprodón, s/n°
Finca La Riba
Vall de Bianya
Gerona, 17813
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Aujeszky 783 + O/W, lyophilisate and solvent for emulsion for injection for pigs

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

Each dose (2 ml contains:

Lyophilisate:
Active substance:
Live attenuated Aujeszky's disease virus, strain NIA_3-783 $\geq 10^{5.2}$ $CCID_{50}$*

*$CCID_{50}$ – the quantity of virus, which infects 50 % of the cell cultures inoculated.

Solvent:
Aluminium hydroxide, Mineral oil (Marcol 52), Mannide mono oleate (Arlacel A), Polysorbate 80 (Tween 80), Thiomersal.

Appearance of the veterinary medicinal product before reconstitution:
Solvent: White, non-transparent liquid
Lyophilisate: Cream coloured lyophilisate

4. INDICATION(S)

Active immunisation of pigs from the age of 10 weeks to prevent the mortality and clinical signs of Aujeszky's disease and to reduce the excretion of Aujeszky's disease field virus.
Passive immunisation of the progeny of vaccinated gilts and sows to reduce mortality and clinical signs of Aujeszky's disease and to reduce the excretion of Aujeszky's disease field virus.

Onset of immunity: 3 weeks after basic vaccination.
Duration of immunity 3 months after basic vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Slight, transient and local reactions up to 2 cm in diameter after first vaccination and up to 5 cm after second vaccination have been very commonly reported to occur in up to 50% of the pigs in laboratory studies and field trials. In general, these reactions disappear within 3 weeks post primary vaccination.

A transient increase in body temperature, up to about 40.5 ^{o}C and lasting for up to 2 days, have been very commonly reported to occur in pigs after vaccination in laboratory studies and field trials.

Hypersensitivity reactions have been reported in very rare cases from spontaneous reports.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

For intramuscular use.

One dose = 2 ml of reconstituted emulsion.

Vaccination programme:

Basic vaccination of fattening pigs and breeding pigs (gilts, sows and boars):
- Inject one dose per fattening pig from the age of 10 weeks. A second dose may be injected 3–4 weeks after the first injection.
- Inject one dose per breeding pig (gilts, sows and boars) from the age of 10 weeks followed by a second injection 3–4 weeks after the first injection.

Re-vaccination of breeding pigs (gilts, sows and boars):
- Inject one dose per gilt before the first mating, or
- Inject one dose per gilt or sow during each gestation at 3–6 weeks before the expected date of farrowing.
- Inject one dose per boar at least every 6 months.

For whole herd vaccination, an injection of one dose may be administered per gilt, sow and boar every 4 months.

9. ADVICE ON CORRECT ADMINISTRATION

To reconstitute the vaccine, inject 3 ml of solvent into the small vial with the lyophilisate. Shake gently to suspend the lyophilisate and transfer the suspended lyophilisate into the vial with the solvent.
To avoid foaming, gently shake the vial after reconstitution of the freeze-dried component in the liquid component. Use sterile syringes and needles. Administer by intramuscular injection of 1 dose (2 ml) per pig in the neck in the area behind the ear.

Appearance of the veterinary medicinal product after reconstitution:
White non-transparent liquid.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

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

Shelf-life after reconstitution according to directions: 1 hour.

12. SPECIAL WARNING(S)

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Special warnings for each target species:
Vaccinate healthy animals only.
The presence of maternal antibodies against Aujeszky's disease virus may have a negative influence on the result of vaccination.

Special precautions for use in animals:
Each piglet of vaccinated gilts or sows should ingest a sufficient quantity of colostrum and milk.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after use.

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interactions with other medicinal products and other forms of interactions:
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 (symptoms, emergency procedures, antidotes):

Apart from an increase in the extent of the tissue reaction at the site of injection, no other undesirable effects have been observed.

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 or pharmacist 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

15. OTHER INFORMATION

The active substance stimulates active immunity against Aujeszky's disease in pigs. By reconstitution of the immunogen in the oil emulsion the stimulation of immunity after injection is prolonged. Progeny of vaccinated gilts and sows derive a passive immunity via the colostrum and milk.
The gE- (glycoprotein E negative) characteristic of the vaccine virus makes it possible to distinguish between antibodies induced by vaccination with this product and those induced by field infection with Aujeszky's disease virus, if the vaccine is used in association with an appropriate diagnostic test. Therefore, the product is suitable to be used in eradication programmes against Aujeszky's disease field virus in pigs based on the presence or absence of antibodies against the gE-antigen of that virus.

Cardboard box of 1 vial of lyophilisate (10 doses) and 1 vial of 20 ml of solvent.
Cardboard box of 1 vial of lyophilisate (50 doses) and 1 vial of 100 ml of solvent.
Cardboard box of 1 vial of lyophilisate (100 doses) and 1 vial of 200 ml of solvent.
Cardboard box of 10 vials of lyophilisate (10 doses) and 10 vials of 20 ml of solvent.
Cardboard box of 10 vials of lyophilisate (50 doses) and 10 vials of 100 ml of solvent.
Cardboard box of 10 vials of lyophilisate (100 doses) and 10 vials of 200 ml of solvent.

Not all pack sizes may be marketed.

Approved: 05 March 2021