ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Lyophilisate:

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

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

Solvent:

Adjuvants:

Aluminium hydroxide	2.1 mg
Mineral oil (Marcol 52)	425 µl
Mannide mono oleate (Arlacel A)	46 µl
Polysorbate 80 (Tween 80)	17 µl

Excipient:

Thiomersal	0.15 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for emulsion for injection.

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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 °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).

4.7 Use during pregnancy, lactation or lay

Can be used 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.

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.

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.

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

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, live viral vaccines for pigs, Aujeszky's disease virus
ATCvet code: QI09AD01.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adjuvants
Aluminium hydroxide
Mineral oil (Marcol 52)
Mannide mono oleate (Arlacel A)
Polysorbate 80 (Tween 80)

Excipients
Thiomersal
Disodium hydrogen phosphate
Sodium dihydrogen phosphate dihydrate
Sodium Chloride
Water for injections

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I hydrolytic glass vials containing 10, 50 or 100 doses of lyophilisate. The vials are closed with a butyl rubber stopper and sealed with an aluminium cap.

Solvent:
Type I hydrolytic glass vials containing 20 ml, 100 ml or 200 ml of solvent or Type II glass rinsed with WFI containing 100 ml or 200 ml of solvent. The vials are closed with a butyl rubber stopper and sealed with an aluminium cap.

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.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/98/009/001-006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07/08/1998.
Date of last renewal: 22/08/2008.

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

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.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICALLY ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substances

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

Name and address of the manufacturers responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce 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 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 ≥ $10^{5.2}$ $CCID_{50}$

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/98/009/001 (1 x 20 ml)
EU/2/98/009/002 (1 x 100 ml)
EU/2/98/009/003 (1 x 200 ml)
EU/2/98/009/004 (10 x 20 ml)
EU/2/98/009/005 (10 x 100 ml)
EU/2/98/009/006 (10 x 200 ml)

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 ≥ $10^{5.2}$ $CCID_{50}$

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/98/009/002 (1 x 100 ml)
EU/2/98/009/003 (1 x 200 ml)
EU/2/98/009/005 (10 x 100 ml)
EU/2/98/009/006 (10 x 200 ml)

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 ≥ $10^{5.2}$ $CCID_{50}$*

*$CCID_{50}$ – 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 °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

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 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.