# 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 $\geq 10^{5.2}$ $CCID_{50}$*

*$CCID_{50}$ – 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.

<u>Basic vaccination of fattening pigs and breeding pigs (gilts, sows and boars):</u>
- 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.

<u>Re-vaccination of breeding pigs (gilts, sows and boars):</u>
- 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: QI09 AD01.

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

## 8. MARKETING AUTHORISATION NUMBER

Vm 42058/5071

## 9. DATE OF FIRST AUTHORISATION

07 August 1998

## 10. DATE OF REVISION OF THE TEXT

March 2021

Approved: 05 March 2021