Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Aujeszky

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml:

Active substance(s)

Aujeszky Disease Virus (porcine Herpesvirus type 1) strain Phylaxia:
equivalent to ≥ 8,2 $\log_{10}$ $CCID_{50}$ (before inactivation)

Adjuvant

dl-α-Tocopherol acetate:	150,00 mg

Preservative

Formalin	1,08 mg

Excipient(s) knowledge of which is essential for the proper administration of the veterinary medicinal product

Excipients to:	2,00 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Aqueous suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (fattening and breeding pigs)

4.2 Indications for use, specifying the target species

Active immunisation of pigs to prevent mortality and clinical signs of Aujeszky's Disease and to reduce the spreading of Aujeszky's Disease virus.
Passive immunisation of the progeny of vaccinated sows, to prevent mortality and to reduce the clinical signs of Aujeszky's Disease.
Duration of active immunity: 5-6 months after the last (re)-vaccination.
Maternal antibodies provide passive immunity to the progeny for at least 1 week.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

None.

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

In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A transient rise in body temperature may occur in pregnant pigs up to 7 hours after vaccination. In rare cases hypersensitivity reactions might occur. A mild and transient swelling at the injection site may be observed for 1-3 days in approxmately 2% of the vaccinated pigs.

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 from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

2 ml per pig via deep intramuscular injection.

Basic vaccination:
First vaccination from the age of 10 weeks onwards,
to be followed by a second vaccination 4-6 weeks after the first vaccination.
All unvaccinated pigs introduced to a farm should be given the basic vaccination.
Booster vaccination:

Single vaccination every 5-6 months.

Breeding pigs:
For optimal protection of the offspring: single revaccination of gilts and sows at 6-2 weeks before farrowing, but within 6 months of the previous vaccination.
Fattenig pigs:
Revaccination of fattening pigs will normally not be necessary.

Eradication scheme:
When used in eradication schemes, the appropriate (re-)vaccination schedule must be followed in accordance with the national requirements.

Maternal antibodies may interfere with the efficacy of the vaccine until the piglets are 10 weeks old.

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

At 2-fold overdose, no other effects than mentioned under section 5.4 have been observed.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI09AA01
Pharmacotherapeutic group: inactivated Aujeszky's disease virus vaccine.
The glycoprotein gE is deleted from the antigen, so that the antibodies which are formed after vaccination can be distinguished from antibodies which are formed after infection with the field virus.
The vaccine is intended to stimulate active immunity against porcine Herpesvirus type I (pseudorabies). The antibodies are passed on to the progeny to provide passive immunity.
dl-α-tocopherol acetate is added as an adjuvant in order to give a prolonged stimulation of immunity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sodium chloride
Water for injection

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product

6.3 Shelf-life

24 months.
Use the product immediately after broaching the vials

6.4 Special precautions for storage

Store at 2-8 °C. Do not freeze. Keep container in the outer carton (protect from light)

6.5 Nature and composition of immediate packaging

Vials of glass (Ph.Eur. type II) or polyethylene terephthalate (PET), closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap, containing 20, 50, 100 or 250 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/85/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th November 2004