Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn i-Aujeszky O/W

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

		Per dose (2 ml)
Active Substance(s):		
Inactivated Aujeszky's Disease Virus (strain Bartha K-61: gE glycoprotein deletion)	Minimum	$10^{8.0}TCID_{50}$
Constituents(s):		
Gentamicin Sulphate	Trace	
Mineral Oil (Marcol 52)		0.45 ml
Mannide mono oleate (Montanide)		0.05 ml
Polysorbate 80		0.018 ml
Aluminium Hydroxide Gel (3%)		0.10 ml
Thimerosal		0.15 mg
Buffered Saline	ad	2 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for Injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Gilts and Pregnant sows.

4.2 Indications for use, specifying the target species

To be used for the vaccination of healthy gilts and pregnant sows to reduce the mortality of piglets due to Aujeszky's disease.

Onset of passive immunity in the piglets is at 7 days of age with the duration lasting 4 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate sick animals.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

This vaccine is not suitable for administration to humans.

Warning to the user:
If you are accidentally injected with this product, go at once to a doctor or to the nearest accident and emergency (casualty) department of a hospital and show the insert of the vaccine to the doctor or nurse on duty.
Warning to the doctor:
Accidental injection with this mineral oil based product may cause a local or systemic reaction.
Expert, prompt, surgical attention is required and may necessitate early incision and irrigation of the injected area especially where there is involvement of the finger pulp or tendon sheaths.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in body temperature (to between 40ºC and 41ºC) may be observed following vaccination, but this should resolve by two days following vaccination.
Swellings up to 5 cm in size may be observed, which will gradually resolve and should be gone by 2 weeks following vaccination. Occasionally small swellings may persist for longer.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy. The safety during lactation has not been examined.

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 Suvaxyn i-Aujeszky O/W.

4.9 Amounts to be administered and administration route

Dosage: 1 dose = 2 ml.

Basic Vaccination Scheme:
Breeding Stock: Rearing gilts have to be given two doses with an interval of 3 to 4 weeks between doses, the first dose at a minimum of 10 weeks of age. A single 2 ml dose should then be given during the subsequent gestation at 3 to 6 weeks before the expected date of farrowing.

The minimum time period between vaccination of gilts and servicing is 2 weeks.

Re-vaccination Scheme:
For the passive protection of piglets born from vaccinated sows the basic vaccination of the sow should be followed by one dose of Suvaxyn i-Aujeszky O/W during each gestation at 3 to 6 weeks before the expected date of farrowing.

ADMINISTRATION
Shake the vial well before use.
Vaccinate only intramuscularly in the neck behind the ear using the correct vaccination techniques.
When administering product from a multi-dose container, use of a multi-dosing automatic syringe is recommended.
Syringes should not have been sterilised chemically or be above ambient temperature.
Avoid stress in the animals around the time of injection.

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

Reactions following a double dose are similar to those observed following administration of a single dose (see 4.3).

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine is intended to induce an active immunity against Aujeszky's disease in sows and gilts to provide passive protection to the piglets.

ATC vet code: Q109AA01.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomerosal
Sodium Chloride
Disodiumhydrogenphosphate
Sodiumdihydrogenphosphate.$2H_2O$
Water for Injection

6.2 Incompatibilities

Do not mix with any other immunological product.

6.3 Shelf-life

Shelf life: 24 months.

6.4 Special precautions for storage

Prevent the vaccine from freezing or exposure to heat and /or direct sunlight. The product is to be stored in the dark at a temperature of +2°C to +8°C in the unopened and undamaged vial.
Once opened, vials must be used immediately.

6.5 Nature and composition of immediate packaging

Vial: Glass Type II (hydrolytic).
Contents: 100 ml in a 100 ml vial (50 doses of vaccine)
Closures: Butyl rubber stoppers Type I with aluminium cap.

Pack sizes: 1 vial of 50 doses
10 vials of 50 doses each.

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

Fort Dodge Animal Health Limited,
Flanders Road,
Hedge End,
Southampton SO30 4QH,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10861/47/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th July 2002