

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Freeze dried vaccine: Suvaxyn® Aujeszky
Diluent: Suvaxyn® Aujeszky Diluent

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

		<u>Per dose (2 ml)</u>
<u>Active Ingredient</u>		
Live Aujeszky’s Disease virus,	not less than 10 ^{5.2} TCID ₅₀ strain	
Bartha K61 (gE glycoprotein deletion).		
Gentamicin sulphate	maximum	5.2 µg
<u>Diluent:</u>		
Excipients	q.s.	2 ml
(which include Phenol Red)		

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and Solvent for Solution for Injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Fattening pigs.

4.2 Indications for use, specifying the target species

For active immunization of pigs to reduce mortality, clinical signs, virus excretion and infection caused by Aujeszky’s Disease Virus. Onset of immunity occurs 1 week after vaccination with duration of immunity lasts 13 weeks.

4.3 Contraindications

Do not vaccinate unhealthy pigs.

4.4 Special warnings for each target species

Animals that have received immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.

Maternally derived antibody (MDA) can interfere with development of active immunity. Where it is likely that recent field infection or vaccination of the dam has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.

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

Avoid accidental self-injection or ingestion. Wash injected area or drink water if ingested. Seek medical advice if symptoms develop following self-administration / ingestion.

4.6 Adverse reactions (frequency and seriousness)

Occasional local injection site reactions up to 5 centimeters and increased temperatures (up to 1° C above normal) may occur following vaccination; these reactions are usually mild and transient (with local reactions disappearing within a week and fever dissipating within 24 hours). In the event of allergic reactions, use epinephrine (adrenaline) and/or a short-acting glucocorticoid.

4.7 Use during pregnancy, lactation or lay

Not recommended for use during pregnancy.

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® Aujeszky.

4.9 Amounts to be administered and administration route

After reconstitution of Suvaxyn® Aujeszky in Suvaxyn® Aujeszky Diluent:
one dose of 2 ml per pig.

VACCINATION SCHEDULE

Feeder-finishing pigs:

Feeder-finishing pigs should be vaccinated at the start of the fattening period, at the minimum age of 10 weeks. To animals vaccinated in the presence of maternal immunity a second vaccination is to be given 3 to 4 weeks later.

ADMINISTRATION

Reconstitute the Suvaxyn® Aujeszky in Suvaxyn® Aujeszky Diluent prior to use. Extract approximately 5 mls of the diluent with a sterile syringe and needle. Inject the diluent into the vial holding the lyophilized Suvaxyn® Aujeszky. Shake the vial gently and using the syringe take up all the reconstituted material and inject it into the original diluent vial. Shake the vial gently so that all the vaccine is well mixed. Use the product immediately after reconstitution.

Syringes and needles should not have been sterilised chemically or be above ambient temperature. Do not use chemicals to disinfect or sterilise skin.

Vaccinate only intramuscularly in the neck behind the ear using the correct vaccination techniques.

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

Administration of an overdose may cause mild, transient fever, lasting up to four days, and local reactions as described for a single dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine is intended to stimulate active immunity against Aujeszky's disease in fattening pigs.

ATC vet code: Q109AD01.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

D-mannitol
Inositol
Peptone
Gelatine

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product except Suvaxyn® Aujeszky Diluent

6.3 Shelf-life

SUVAXYN Aujeszky: 36 months.

SUVAXYN Aujeszky Diluent: 36 months.

Reconstituted vaccine: Use immediately on reconstitution.

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 its unopened and undamaged package.

6.5 Nature and composition of immediate packaging

Suvaxyn® Aujeszky:

- Nature: glass, hydrolytic class I; capacity 7 ml containing 10, 50 or 100 doses.
- Closure: Butylrubber stopper + Aluminium cap
- Contents: freeze dried pellet

Suvaxyn® Aujeszky Diluent:

- Nature: glass, hydrolytic class I (10 dose presentation) or II (50 and 100 dose presentation)
- Closure: Butylrubber stopper + Aluminium cap
- Contents: 22 ml, 105 ml or 210 ml for respectively the 10, 50 or 100 dose presentation

Pack sizes: 1 x 10 dose, 50 dose or 100 dose

10 x 10 dose, 50 dose or 100 dose

Not all pack sizes may be marketed

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant 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. 10861/48/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18th September 2002