IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10996/077/001**
Case No: 7008128

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Porcilis Begonia DF Lyophilisate and solvent for suspension for intramuscular injection in pigs

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **05/07/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Begonia DF.
Lyophilisate and solvent for suspension for intramuscular injection in pigs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyophilisate:
Active substance: Live Aujeszky's disease virus strain Begonia (gE^-, tk^-): $10^{5.5}$ - $10^{6.5}$ $TCID_{50}$* per dose of 2 ml.

Solvent (Diluvac Forte):
Adjuvant: dl-α-tocopheryl acetate: 75.0 mg/ml

Excipients:
For a full list of excipients, see section 6.1.

* $TCID_{50}$: tissue culture infective dose 50%

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for intramuscular injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

Active immunisation of pigs against Aujeszky's disease (Pseudorabies) to prevent mortality and clinical signs as well as to reduce replication of Aujeszky's disease virus.
Onset of immunity: 3 weeks.
Duration of immunity: approximately 4 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Pigs younger than 3 months of age, with maternal antibodies, may need revaccination (see vaccination scheme).

4.5 Special precautions for use

Special precautions for use in animals

Do not use in dogs.

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 leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In rare cases an allergic (hypersensitivity) reaction may occur. In such cases appropriate treatment (antihistamine, adrenaline) can be given by the veterinarian, if necessary.
A slight rise in body temperature, during approximately 7 hours to one day, may occur in some vaccinated animals. No or very limited local reactions were observed during safety testing (inflammatory reaction of ≤ 2 cm during approximately 14 days in 7 of 10 animals)
In the dog (not a target species) neurological signs may occur after intramuscular injection. After oral administration to dogs no adverse reactions are observed.

4.7 Use during pregnancy, lactation or lay

This vaccine 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 products. A decision to use this vaccine before or after any veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Reconstitute the vaccine pellet with 2 ml diluent per dose. After reconstitution, administer 1 dose of 2 ml product via intramuscular injection.

Vaccination scheme:

Fattening pigs:
When pigs are vaccinated from the age of 14 weeks, no revaccination is needed.
In situations with a risk of early infection, pigs can be vaccinated as young as 10 weeks of age, but should be re-vaccinated at the age of at least 14 weeks, with an interval of at least 2 weeks after the first vaccination, because the presence of maternal antibodies against Aujeszky's disease may have a negative influence on the result of early vaccination.

Breeding pigs:
Basic vaccination as for fattening pigs
Revaccinations at 4-month intervals, three times yearly as herd vaccination.

Eradication scheme:
When used in eradication schemes the appropriate (re-)vaccination schedule should be followed.

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

At ten times the maximum dose, the symptoms are not different from those mentioned after a single dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pig, live viral vaccine.
ATCvet code: QI09AD01.

To stimulate active immunity against Aujeszky's Disease. The virus strain is thymidine kinase and glycoprotein gE negative (tk^-, gE^-), genetically stable and does not persist in the pigs. Vaccination allows the discrimination from field infections (marker vaccine).
The solvent has adjuvant properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
culture medium,
chemically defined stabilizer CD#156 (patented)

Solvent (Diluvac Forte):
polysorbate 80
simethicone
sodium chloride
potassium and sodium phosphate buffers
water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the solvent recommended for use with the product.

6.3 Shelf-life

Shelf life of the veterinary product as packaged for sale
Lyophilisate: 18 months (following storage at -20°C for max 24 months by the manufacturer)
Solvent: in glass vials 4 years, in PET vials 2 years
Shelf life after reconstitution according to directions: 8 hours

6.4 Special precautions for storage

Lyophilisate: Store in a refrigerator (2°C -8°C). Do not freeze. Protect from light.
Solvent: Store below 25°C. Do not freeze.
After reconstitution: Store in a refrigerator at 2-8°C.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Glass vials, hydrolytical class Type I, closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap, containing a freeze-dried plug of 10, 25, 50 or 100 doses of vaccine.

Solvent:
Vials of PET or glass, hydrolytical class Type I or II, closed with a butyl rubber stopper and sealed with an aluminium cap, containing 20, 50, 100 or 200 ml of solvent.

Authorised pack size: 1, 5 and 10 vials of the same content per carton box.
Solvent may be packed together with the lyophilisate vials or separately.
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, approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/077/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th May 2010

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Porcilis Begonia DF is restricted or prohibited in Ireland pursuant to national animal health policy.

Any person intending to import, sell supply and/or use Porcilis Begonia DF must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.