SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Begonia Diluvac (DE)
Porcilis Begonia Diluvac Forte (BE)
Porcilis Begonia DF (LU, EL, ES, IE, PT, UK)
Porsilis Begonia (IT)
Porcilis AD Begonia (NL)
Begonia Aujeszky (FR)

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

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 and lactation

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 solvent 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)

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

4.11 Withdrawal period

Zero days

5. 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 product or waste materials derived from the use of such products, if appropriate

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 International B.V.
Wim de Körverstraat 35
NL 5831 AN Boxmeer
represented by the national companies in the Concerned Member States

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

CVMP concertation procedure concluded: 18-12-1991
MR renewal dates: 19.02.2005/19.02.2010

10. DATE OF REVISION OF THE TEXT

January 2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

The use of Porcilis Begonia DF may be prohibited or subject to special regulations in certain Member States. Any person intending to use this vaccine must consult the relevant Member State's competent authority on the current vaccination policies before use.