SPC

Porcilis® Begonia

MSD Animal Health

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Begonia IDAL (DE, BE, EL, ES, PT, IE, UK)
Porsilis Begonia IDAL (IT)
Porcilis AD Begonia IDAL (NL)
Begonia Aujeszky IDAL (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Each dose contains at least $10^{5.5}$ $TCID_{50}$ and maximum $10^{6.5}$ $TCID_{50}$ of Aujeszky's disease virus strain Begonia.

Composition of diluent (Diluvac Forte)
Phosphate buffered saline

Adjuvant: dl-α-tocopheryl acetate 75.0 mg/ml
For a list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Freeze-dried pellet and diluent for suspension for intradermal 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.

S. pecial precautions to be taken by the person administering the medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)
In rare cases a hypersensitivity-like reaction may occur.
A slight rise in body temperature, during approximately 7 hours to one day, may occur in some vaccinated animals.
Immediately after the intradermal administration of the vaccine, the volume of the vaccine can be seen in the skin as a small papule, which will disappear within approximately 48 hours.
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 from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route
Reconstitute the vaccine pellet with 0.2 ml diluent per dose. After reconstitution, administer 1 dose of 0.2 ml product via intradermal application, using an intradermal injection device.

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 under 4.6 after single dose.

4.11 Withdrawal period
Zero days
(Not applicable, if not required according to national law.)

5. IMMUNOLOGICAL PROPERTIES

Live viral vaccine to stimulate active immunity against Aujeszky's Disease.
ATCvet code: QI09AD01.
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 diluent has adjuvant properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lyophilisate:
culture medium, chemically defined stabilizer CD#156 (patented)
Diluent (Diluvac Forte):
dl-α-tocopheryl acetate, polysorbate 80, simethicone, sodium chloride, potassium and sodium phosphate buffers, water for injection.

6.2 Incompatibilities
Do not mix with other products except the diluent recommended for use with the product.

6.3 Shelf life
-Freeze-dried virus:
18 months (following storage at -20°C for max 24 months by the manufacturer)
-Diluent Glass: 4 years, PET: 2 years
-reconstituted vaccine: 8 hours

6.4 Special precautions for storage
Freeze-dried virus: Storage at 2-8°C. Keep in the outer carton (sensitivity to light).
Diluent: Storage below 25°C.
Do not freeze.
After reconstitution: Storage at 2-8°C.

6.5 Nature and composition of immediate packaging
-Freeze-dried virus:
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.

- Diluent:
Vials of PET or glass, hydrolytical class Type I or II, closed with a butyl rubber stopper and sealed with an aluminium cap, containing 2, 5, 10 or 20 ml (glass) or 20 ml (PET) of diluent.

Authorised pack size: 1, 5 and 10 vials of the same content per carton box.
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: 28-09-1994
MR renewal date: 04.01.2005

10. Date of revision of the text

January 2008

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable