SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Begonia DF lyophilisate and solvent for emulsion for injection for pigs
Porcilis Begonia Diluvac Forte (BE)
Porcilis Begonia Diluvac (DE)
Porcilis Begonia DF (LU, EL, ES, IE, PT, UK(XI))
Porsilis Begonia (IT)
Porcilis AD Begonia (NL)
Begonia Aujeszky (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) of reconstituted vaccine contains:

Active substance:
Aujeszky's disease virus, strain Begonia gE^- tk^-, live: $10^{5.5}$ - $10^{6.5}$ $TCID_{50}$*

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

Adjuvant:
dl-α-tocopheryl acetate: 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Culture medium
Chemically defined stabilizer CD#156 (patented)
Solvent (Diluvac Forte):
Polysorbate 80
Simethicone
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injections

Lyophilisate: pellet.
Solvent: white opalescent emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each 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 after vaccination.

Duration of immunity: approximately 4 months after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Do not use in dogs.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Pigs younger than 3 months of age, with maternal antibodies, may need revaccination (see vaccination scheme).

Special precautions to be taken by the person administering the veterinary 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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
The safety and efficacy of the veterinary medicinal product in non-target species such as dogs has not been evaluated. In the dog (not a target species) adverse events including neurological signs may occur after intramuscular injection.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10.000 animals treated):	Hypersensitivity reaction[1]. Elevated temperature[2].
Very rare (<1 animal / 10.000 animals treated, including isolated reports):	Injection site reaction[3].

[1] In such cases appropriate treatment (e.g. antihistamine, adrenaline) should be administered by the veterinarian, if necessary.
[2] During approximately 7 hours to one day.
[3] Inflammatory reaction of ≤ 2 cm during approximately 14 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

This vaccine can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

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

Visual appearance after reconstitution: white emulsion.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

<Official control authority batch release is required for this product according to national requirements.>

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal 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.

5.3 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 °C – 8 °C.

5.4 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.

Pack sizes:
Lyophilisate: Cardboard box with 1, 5 and 10 vials of 10, 25, 50 or 100 doses.
Solvent: Cardboard box with 1, 5 and 10 vials of 20, 50, 100 or 200 ml.
Solvent may be packed together with the lyophilisate vials or separately.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Begonia Diluvac lyophilisate and solvent for emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Aujeszky's disease virus, strain Begonia gE^- tk^-, live: $10^{5.5}$ - $10^{6.5}$ $TCID_{50}$

3. PACKAGE SIZE

1x 10 doses
1x 25 doses
1x 50 doses
1x 100 doses
5x 10 doses
5x 25 doses
5x 50 doses
5x 100 doses
10x 10 doses
10x 25 doses
10x 50 doses
10x 100 doses

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze. Protect from light.
Keep refrigerated after reconstitution.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate Glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Begonia Diluvac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Per dose of 2 ml:
Aujeszky's disease virus, strain Begonia gE^- tk^-, live: $10^{5.5}$ - $10^{6.5}$ $TCID_{50}$

10 doses
25 doses
50 doses
100 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 8 hours.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

PET and glass vials label - Solvent

1. NAME OF THE SOLVENT

Diluvac Forte
Adjuvated solvent for lyophilisates

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml
100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis Begonia Diluvac lyophilisate and solvent for emulsion for injection for pigs

2. Composition

Each dose (2 ml) of reconstituted vaccine contains:

Active substance:
Aujeszky's disease virus, strain Begonia gE^- tk^-, live: $10^{5.5}$ - $10^{6.5}$ $TCID_{50}$ *
* $TCID_{50}$: tissue culture infective dose 50%

Adjuvant:
dl-α-tocopheryl acetate: 150 mg

Lyophilisate: pellet.
Solvent: white opalescent emulsion.

3. Target species

Pigs.

4. Indications for use

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 after vaccination.

Duration of immunity: approximately 4 months after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Do not use in dogs.
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Pigs younger than 3 months of age, with maternal antibodies, may need revaccination (see vaccination scheme).

Special precautions to be taken by the person administering the veterinary 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.

Other precautions:
The safety and efficacy of the veterinary medicinal product in non-target species such as dogs has not been evaluated. In the dog (not a target species) adverse events including neurological signs may occur after intramuscular injection.

Pregnancy and lactation:
This vaccine can be used during pregnancy and lactation.

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 other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:
No adverse events other than those mentioned in section 'Adverse events' were observed after administration of a 10-fold overdose of the vaccine.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

<Official control authority batch release is required for this product according to national requirements.>

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

7. Adverse events

Pigs:

Rare (1 to 10 animals / 10.000 animals treated):	Hypersensitivity reaction[1]. Elevated temperature[2].
Very rare (<1 animal / 10.000 animals treated, including isolated reports):	Injection site reaction[3].

[1] In such cases appropriate treatment (e.g. antihistamine, adrenaline) should be administered by the veterinarian, if necessary.
[2] During approximately 7 hours to one day.
[3] Inflammatory reaction of ≤ 2 cm during approximately 14 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Reconstitute the vaccine pellet with 2 ml solvent per dose. After reconstitution, administer 1 dose of 2 ml product via intramuscular application, using an intramuscular 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.

9. Advice on correct administration

Visual appearance after reconstitution: white emulsion.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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 °C – 8 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 8 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Lyophilisate: Cardboard box with 1, 5 and 10 vials of 10, 25, 50 or 100 doses.
Solvent: Cardboard box with 1, 5 and 10 vials of 20, 50, 100 or 200 ml.
Solvent may be packed together with the lyophilisate vials or separately.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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.