SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Glässer Vet Suspension for injection for pigs (DK-FI-NO)
Porcilis Glässer Suspension for injection for pigs (AT-BE-DE-EL-ES-FR-IE-LU-NL-PT-UK-CY-CZ-SK-SI-HU-PL-EE-LV)
Porsilis Glässer Suspension for injection for pigs (IT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml

Active substance(s):
Inactivated whole bacterial cells of *Haemophilus parasuis* serotype 5, strain 4800: 0.05 mg total nitrogen, inducing ≥ 9.1 Elisa Units[*] .

Adjuvant:
150 mg dl-α-tocopheryl acetate

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

3. PHARMACEUTICAL FORM

Suspension for injection
Appearance: aqueous, white or nearly white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and sows.

4.2 Indications for use, specifying the target species

Pigs:
Active immunisation of pigs to reduce typical lesions of Glässer's disease caused by *Haemophilus parasuis* serotype 5.
Onset of immunity: 2 weeks after completion of vaccination.
Duration of immunity: 14 weeks after completion of vaccination.

Sows:
For passive immunisation of the progeny of vaccinated sows and gilts to reduce infection, mortality, clinical signs and typical lesions of Glässer disease caused by *Haemophilus parasuis* serotype 5 and to reduce clinical signs and mortality caused by *Haemophilus parasuis* serotype 4.
Onset of immunity: After birth and sufficient uptake of colostrum.
Duration of immunity has been demonstrated at 4 weeks of age against serotype 4 and at 6 weeks of age against serotype 5.

4.3 Contraindications

None.

[*] ELISA units = mean antibody titre (log2 value) in the potency test in mice.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals. In the event of anaphylactic reaction consult your veterinarian.

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.

4.6 Adverse reactions (frequency and seriousness)

Pigs:
A transient increase in temperature (≤ 2°C) in combination with signs of general discomfort, such as less activity, depression and vomiting may occur on the day of vaccination. The next day the animals are back to normal. Local reactions (painless reddish swellings of 2,5-7,5 cm) may be observed in some pigs until 3 days after vaccination. Systemic anaphylactic reactions may occur in very rare cases (e.g. less than 1 animal in 10,000 animals).

Sows:
A transient increase in temperature may occur (mean 0.9°C, with individual animals displaying a temperature increase of above 2°C). A tendency to lie down, reduced feed and water intake and minor signs of illness may be observed 1 to 2 days after vaccination. All animals return to normal within 1 to 3 days after vaccination. Transient local reactions consisting mostly of non-painful swellings with a diameter smaller than 10 cm may be observed. In some cases swelling may be warm, red and painful with a size larger than 10 cm. These local reactions disappear or clearly diminish 14 days after vaccination.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Allow vaccine to reach ambient temperature. Shake well before use.
Administer 2 ml (one dose) of the vaccine intramuscularly in the neck of the pig.

The vaccine is of benefit when pigs and sows with no or low levels of antibodies against H. parasuis serotype 5 are mixed with animals from or in an environment with higher prevalence of Glässers disease or if the piglets from sows with no or low antibodies are reared in such environment. Vaccination of sows with moderate to high levels of antibodies has not been shown to provide additional protection of the offspring. The control of Glässers disease is also dependent on management factors and reduction of stress.
Antibodies against H. parasuis serotype 5 have been shown to be cross-reactive against H. parasuis serotype 4.

Vaccination scheme pigs:
Vaccinate pigs of at least five weeks of age twice with an interval of two weeks.

Vaccination scheme sows:
Vaccinate sows at 6 to 8 weeks before expected time of farrowing twice with an interval of four weeks.

Revaccination scheme sows:
For sows vaccinated during the previous pregnancy, a single revaccination at 4 to 2 weeks before farrowing is recommended.

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

Pigs:
After vaccination with a twofold overdose, reactions are not different from those after the single dose.

Sows:
After vaccination with a twofold overdose, a transient increase in temperature may occur (mean 1.8 °C, with a maximum observed temperature of 41.3 °C). Other reactions are not different from those after a single dose.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccine.
ATC vet code: QI 09AB07.

The product stimulates the development of active immunity against *Haemophilus parasuis* serotype 5. Serotype 5 is the most prevalent under the virulent serotypes of *H. parasuis.* There is some cross protection to the other virulent serotypes, but full cross protection cannot be assured. The product stimulates transfer of passive immunity against *Haemophilus parasuis* serotype 5 and 4 to the progeny after vaccination of pregnant sows. It contains an aqueous adjuvant.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

phosphate buffer
simethicone
water for injections
polysorbate 80

6.2 Imcompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale

PET vials: 2 years
Glass vials: 1 year

Shelf-life after first opening the immediate packaging

Use broached vials immediately.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C)
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Vials of PET or Glass type I (Ph. Eur.) containing 20 ml (10 dose presentation), 50 ml (25 dose presentation) or 100 ml (50 dose presentation), closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Porcilis Glässer is presented in cartons containing 1, 6 or 12 vials of 20 ml, 50 ml or 100 ml.
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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

The national representatives of

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

13-03-2003 / 13-03-2008.

10. DATE OF REVISION OF THE TEXT

15 October 2008.

PROHIBITION OF SALE, SUPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Glässer Vet (DK-FI-NO)
Porcilis Glässer (AT-BE-DE-EL-ES-FR-IE-LU-NL-PT-UK-CY-CZ-SK-SI-HU-PL-EE-LV)
Porsilis Glässer (IT)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:
Inactivated whole bacterial cells of *Haemophilus parasuis* serotype 5, strain 4800:
0.05 mg total nitrogen, inducing ≥ 9.1 Elisa Units[*] .
150 mg dl-α-tocopheryl acetate.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10/25/50 doses

5. TARGET SPECIES

Pigs and sows

6. INDICATION(S)

For active and passive immunisation against Glässer's disease

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m. injection of 2 ml

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use. [This statement will only be printed once]

10. EXPIRY DATE

EXP {month/year}

[*] ELISA units = mean antibody titre (log2 value) in the potency test in mice.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.
Once broached, use immediately.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

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

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

The national representatives of
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Glässer Vet (DK-FI-NO)
Porcilis Glässer (AT-BE-DE-EL-ES-FR-IE-LU-NL-PT-UK-CY-CZ-SK-SI-HU-PL-EE-LV)
Porsilis Glässer (IT)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 2 ml:
≥ 9.1 Elisa Units, H. parasuis, serotype 5 .

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

10/25/50 doses

4. ROUTE(S) OF ADMINISTRATION

i.m. injection

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch/Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use immediately

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Porcilis Glässer Vet (DK-FI-NO)
Porcilis Glässer (AT-BE-DE-EL-ES-FR-IE-LU-NL-PT-UK-CY-CZ-SK-SI-HU-PL-EE-LV)
Porsilis Glässer (IT)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer for the batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Glässer Vet (DK-FI-NO)
Porcilis Glässer (AT-BE-DE-EL-ES-FR-IE-LU-NL-PT-UK-CY-CZ-SK-SI-HU-PL-EE-LV)
Porsilis Glässer (IT)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Suspension for injection
Per dose of 2 ml vaccine:
Inactivated whole bacterial cells of *Haemophilus parasuis* serotype 5, strain 4800:
0.05 mg total nitrogen, inducing ≥ 9.1 Elisa Units[*] .
150 mg dl-α-tocopheryl acetate.

4. INDICATION(S)

Pigs:
Active immunisation of pigs to reduce typical lesions of Glässer's disease caused by *Haemophilus parasuis* serotype 5.
Onset of immunity: 2 weeks after completion of vaccination.
Duration of immunity: 14 weeks after completion of vaccination.

Sows:
For passive immunisation of the progeny of vaccinated sows and gilts to reduce infection, mortality, clinical signs and typical lesions of Glässer disease caused by *Haemophilus parasuis* serotype 5 and to reduce clinical signs and mortality caused by *Haemophilus parasuis* serotype 4.
Onset of immunity: After birth and sufficient uptake of colostrum.
Duration of immunity has been demonstrated at 4 weeks of age against serotype 4 and at 6 weeks of age against serotype 5.

[*] ELISA units = mean antibody titre (log2 value) in the potency test in mice.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Pigs:
A transient increase in temperature (≤ 2°C) in combination with signs of general discomfort, such as less activity, depression and vomiting may occur on the day of vaccination. The next day the animals are back to normal. Local reactions (painless reddish swellings of 2,5-7,5 cm) may be observed in some pigs until 3 days after vaccination. Systemic anaphylactic reactions may occur in very rare cases (e.g. less than 1 animal in 10,000 animals).

Sows:
A transient increase in temperature may occur (mean 0.9°C, with individual animals displaying a temperature increase of above 2°C). A tendency to lie down, reduced feed and water intake and minor signs of illness may be observed 1 to 2 days after vaccination. All animals return to normal within 1 to 3 days after vaccination. Transient local reactions consisting mostly of non-painful swellings with a diameter smaller than 10 cm may be observed. In some cases swelling may be warm, red and painful with a size larger than 10 cm. These local reactions disappear or clearly diminish 14 days after vaccination.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs and sows

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular injection of 2 ml in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

Allow vaccine to reach ambient temperature.
Shake well before use.
Administer 2 ml (one dose) of the vaccine intramuscularly in the neck of the pig.
Use sterile vaccination equipment

Vaccination scheme pigs:
Vaccinate pigs of at least five weeks of age twice with an interval of two weeks.

Vaccination scheme sows:
Vaccinate sows and gilts at 6 to 8 weeks before expected time of farrowing twice with an interval of four weeks.

Revaccination scheme sows:
For sows vaccinated during the previous pregnancy, a single revaccination at 4 to 2 weeks before farrowing is recommended.

The vaccine is of benefit when pigs and sows with no or low levels of antibodies against H. parasuis serotype 5 are mixed with animals from or in an environment with higher prevalence of Glässers disease or if the piglets from sows with no or low antibodies are reared in such

environment. Vaccination of sows with moderate to high levels of antibodies has not been shown to provide additional protection of the offspring. The control of Glässers disease is also dependent on management factors and reduction of stress.
Antibodies against H. parasuis serotype 5 have been shown to be cross-reactive against H. parasuis serotype 4.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.
Use broached vials immediately.

12. SPECIAL WARNING(S)

Vaccinate only healthy animals. In the event of anaphylactic reaction consult your veterinarian.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Can be used during pregnancy.

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

Pigs:
After vaccination with a twofold overdose, reactions are not different from those after the single dose.

Sows:
After vaccination with a twofold overdose, a transient increase in temperature may occur (mean 1.8 °C, with a maximum observed temperature of 41.3 °C). Other reactions are not different from those after a single dose.

Do not mix with any other vaccine or immunological product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Porcilis Glässer is presented in cartons containing 1, 6 or 12 vials of 20 ml, 50 ml or 100 ml.
Not all pack sizes may be marketed.

For animal treatment only.

The product stimulates the development of active immunity against *Haemophilus parasuis* serotype 5. Serotype 5 is the most prevalent under the virulent serotypes of *H. parasuis.* There is some cross protection to the other virulent serotypes, but full cross protection cannot be assured. The product stimulates transfer of passive immunity against *Haemophilus parasuis* serotype 5 and 4 to the progeny after vaccination of pregnant sows. It contains an aqueous adjuvant.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.