

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Glässer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml:

Active substance:

Glaesserella parasuis serotype 5, strain 4800, inactivated**: 0.05 mg total nitrogen, inducing ≥ 9.1 Elisa Units*

* mean antibody titre (\log_2 value) in the potency test in mice

**formerly known as *Haemophilus parasuis*

Adjuvant:

dl- α -tocopheryl acetate 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Phosphate buffer
Simethicone
Polysorbate 80
Water for injections

Aqueous, white or nearly white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs and sows.

3.2 Indications for use for each target species

Pigs:

Active immunisation of pigs to reduce typical lesions of Glässer's disease caused by *G. 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 *G. parasuis* serotype 5 and to reduce clinical signs and mortality caused by *G. parasuis* serotype 4.

Onset of immunity: After birth and sufficient uptake of colostrum.

Duration of immunity: 4 weeks of age against serotype 4 and 6 weeks of age against serotype 5.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ , Discomfort ² , Decreased activity ² , Depression ² ; Injection site swelling ³ , Injection site reddening ³
Common (1 to 10 animals / 100 animals treated):	Vomiting ²
Very rare (<1 animal / 10.000 animals treated, including isolated reports):	Anaphylactic-type reaction ⁴

¹ ≤ 2 °C.

² May occur on the day of vaccination. The next day returning to normal.

³ Painless reddish swellings of 2.5-7.5 cm 3 days after vaccination.

⁴ In the event of anaphylactic reaction consult your veterinarian. In such cases appropriate treatment should be administered without delay.

Sows:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ , Lying down ² , Reduced food intake ² , Decreased drinking ² ; Injection site swelling ³ , Injection site reddening ³ , Injection site warmth ³ , Injection site pain ³
Common (1 to 10 animals / 100 animals treated):	General illness ²

¹ Mean 0.9 °C, with individual animals displaying a temperature increase of above 2 °C.

² May be observed 1 to 2 days after vaccination. All animals return to normal within 1 to 3 days after vaccination.

³ Mostly non-painful swellings < 10 cm in diameter. In some cases, swelling may be warm, red, and painful > 10 cm in diameter. These reactions disappear or clearly diminish 14 days after vaccination.

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:

Can be used during pregnancy.

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 product.

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.

3.9 Administration routes and dosage

Intramuscular use.

Allow vaccine to reach ambient temperature. Shake well before use.

Administer 2 ml (one dose) of the vaccine intramuscularly in the neck.

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.

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

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.

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

Not applicable.

3.12 Withdrawal periods

Zero days

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI 09AB07.

The product stimulates the development of active immunity against *G. parasuis* serotype 5. Serotype 5 is the most prevalent under the virulent serotypes of *G. 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 *G. parasuis* serotype 5 and 4 to the progeny after vaccination of pregnant sows. It contains an aqueous adjuvant.

The vaccine is of benefit when pigs and sows with no or low levels of antibodies against *G. 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 *G. parasuis* serotype 5 have been shown to be cross-reactive against *G. parasuis* serotype 4.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

PET vials: 3 years.

Glass vials: 1 year.

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

5.4 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.

Pack sizes:

Cardboard box containing 1, 6 or 12 vials of 20 ml, 50 ml or 100 ml.

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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/179/001

8. DATE OF FIRST AUTHORISATION

04/03/2004

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

27/09/2024

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>).

