1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PG 600 Powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each reconstituted 5 ml dose contains:

Active substances:

Gonadotrophin, Chorionic Ph. Eur	200 IU
Serum gonadotrophin	400 IU

Excipients:

Qualitative composition of excipients and other constituents
Mannitol
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate

Powder for injection: White to almost white powder.
Solvent: Clear, colourless.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

Gilts: Administration of a single dose of the veterinary medicinal product to gilts over the age of five months will normally result in a fertile oestrus within five days.

Sows post-weaning: To promote early post-partum oestrus (particularly where early weaning is practised) it is recommended that a single injection of the veterinary medicinal product be given within 48 hours of weaning.

Barren sows: Cases of suboestrus or anoestrus due to hormonal imbalance may respond favourably to a single dose of the veterinary medicinal product, exhibiting normal heat within five days of injection.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or any of the excipients.
Do not inject into the subcutaneous fat.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection seek medical advice 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 rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[1]

[1] In case of an anaphylactic reaction, 1-3ml Adrenaline 1:1000 solution should be given by intramuscular injection.

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 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:
Not indicated for use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For intramuscular use.
One dose (5 ml of reconstituted product, equivalent to 200 IU chorionic gonadotrophin and 400 IU serum gonadotrophin) should be aseptically injected intramuscularly, e.g. at the base of the ear using a 1.5” needle which must be directed horizontally.

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

No specific treatment or antidote is recommended.

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

Meat and offal: Zero days

4. PHARMACOLOGICAL or IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QG03GA99

4.2 Pharmacodynamics

The veterinary medicinal product contains the naturally occurring hormones chorionic gonadotrophin and serum gonadotrophin. Serum gonadotrophin has activity broadly similar to FSH (Follicle Stimulating Hormone) whilst chorionic gonadotrophin is broadly similar to LH (Luteinising Hormone).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent or other component supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Store in refrigerator (2 ℃ to 8 ℃).
Protect from light.
Store reconstituted product in a refrigerator (2 ℃ to 8 ℃).
Keep container in outer carton.

5.4 Nature and composition of immediate packaging

Freeze dried powder:
Clear, colourless, glass Type I (Ph. Eur) vials with halogenated butyl rubber stopper, closed with a colour coded aluminium cap, containing a single dose or 5 doses of freeze dried powder for injection.

Solvent:
5 ml presentation:
Clear, colourless, glass Type I (Ph. Eur.) vials with halogenated butyl rubber stopper, closed with a colour coded aluminium cap, containing 5 ml solvent.

25 ml presentation:
Clear, colourless glass Type II (Ph. Eur.) vials with halogenated butyl rubber stopper, closed with a colour coded aluminium cap, containing 25 ml solvent.

Package presentations:
Cartons containing 5 powder vials (1 dose) and 5 solvent vials.
Cartons containing 1 powder vial (5 dose) and 1 solvent vial.

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 Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/025/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

26/08/2024

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).