SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PG 600, Powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each reconstituted 5ml 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
Water for Injections

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For the promotion of a fertile oestrous cycle in gilts and in sows post-weaning and the treatment of suboestrus or anoestrus in barren sows due to hormonal imbalance.

3.3 Contraindications

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:
When administered by the subcutaneous route, care must be taken to avoid injection into subcutaneous fat. In the unlikely event of an individual anaphylactic reaction, 1 – 3 ml adrenaline 1:1000 solution should be given by intramuscular injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

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

3.6 Adverse events

Pigs:
None known.

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:
Not indicated for use during pregnancy. The injection of the veterinary medicinal product into a pregnant sow or gilt will fail to produce heat and will not cause abortion.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Reconstitution: Reconstitute by injecting approximately 2 ml of the solvent provided into the hormone vial, ensure the freeze-dried plug is fully dissolved, and re-inject the resulting solution into the solvent vial. Shake well before use. Reconstituted solution is colourless.

Intramuscular or subcutaneous use.

Sows and gilts: One dose (5 ml) of reconstituted veterinary medicinal product should be aseptically injected subcutaneously or preferably, intramuscularly, at the base of the ear using a 1.5" needle, which must be directed horizontally.

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 is 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.

If corpora lutea are present on the ovary when the veterinary medicinal product is administered, the sow or gilt will fail to respond. For this reason, if an anoestrus sow or gilt fails to respond to the veterinary medicinal product, wait 10 days before repeating the injection.

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

No specific treatment or antidote 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 INFORMATION

4.1 ATCvet code: QG03GA99.

4.2 Pharmacodynamics

The veterinary medicinal product is a freeze-dried presentation of hCG and PMSG in combination with solvent for reconstitution. The veterinary medicinal product contains 400 IU of PMSG and 200 IU of hCG. PMSG and hCG are two large glycoproteins composed of two non-covalently associated alpha and beta subunits. The extensive glycosylation of the CTP tail of the beta subunits of PMSG and hCG results in the extended half-life typical of both hormones which

reaches, in pigs, 36 and 27 hours for hCG and PMSG respectively. PMSG displays dual FSH and LH activities. It therefore stimulates follicular growth and follicular maturation during the days preceding oestrus and ovulation. HCG displays only LH like activity. It therefore plays a key role in the induction of ovulation of the follicles stimulated to grow by PMSG. This explains why the veterinary medicinal product efficiently induces and synchronises puberty (gilts) and the first post weaning ovulation (sows).

4.3 Pharmacokinetics

After injection to pigs, PMSG and hCG are rapidly absorbed as, for both hormones, C_{max} is reached within 8 hours for both hormones. Bioavailability following intramuscular injection is high. In pigs, the elimination half-lives of PMSG and hCG were shown to be 36 and 27 hours respectively.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent 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 at 2 °C – 8 °C.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Reconstituted product should be stored no longer than 24 hours at 2 °C – 8 °C.
Discard unused solution.
This product does not contain a preservative.

5.4 Nature and composition of immediate packaging

Freeze dried powder: Colourless glass Type I vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing a single dose or 5 doses.

Solvent: Colourless glass Type I vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing 5 ml, or clear, colourless neutral glass Type II vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing 25 ml solvent.

Pack sizes:
Cardboard box with 5 x single dose powder vials and 5 x 5 ml solvent vials.
Cardboard box with 1 x 5 doses powder vial and 1 x 25 ml solvent vial.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4095

8. DATE OF FIRST AUTHORISATION

27 July 1994

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 13 October 2025