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 5 ml dose contains:

Active Substances

Chorionic gonadotrophin	200	IU
Serum gonadotrophin	400	IU

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.
Sterile white powder supplied with clear, colourless solvent.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

Gilts: Administration of a single dose of PG 600 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 PG 600 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 PG600, exhibiting normal heat within five days of injection.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance.
Do not inject into the subcutaneous fat.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

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 to the physician.

4.6 Adverse reactions (frequency and seriousness)

In the unlikely event of an individual anaphylactic reaction, 1-3 ml Adrenaline 1:1000 solution should be given by intramuscular injection.

4.7 Use during pregnancy, lactation or lay

Not indicated for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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. Do not inject into subcutaneous fat.

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

No specific treatment or antidote is recommended.

4.11 Withdrawal Period(s)

Meat and offal: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genitourinary system and sex hormones, gonadotrophins, combinations.
ATCvet code: QG03GA99

5.1 Pharmacodynamic properties

PG 600 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).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate

6.2 Incompatibilities

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

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

25ml presentation:
Clear, colourless glass Type II (Ph. Eur.) vials with halogenobutyl 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/025/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th September 2009

10 DATE OF REVISION OF THE TEXT

February 2013