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:

Chorionic gonadotrophin	200 iu
Serum gonadotrophin	400 iu

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection
White powder and clear colourless solution. Reconstituted solution is colourless.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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.

4.3 Contra-indications

Do not inject into the subcutaneous fat.

4.4 Special warning for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals.

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.

ii. Special precautions to be taken by the person administering the medicinal product to the animals.

Care should be taken to avoid accidental self-injection; if accidental self-injection occurs, seek medical advice and show the doctor this label. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy or lactation

Not indicated for use during pregnancy. The injection of PG 600 into a pregnant sow or gilt will fail to produce heat and will not cause abortion.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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 diluent vial. Shake well before use.

One dose (5 ml of reconstituted 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 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 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 product, exhibiting normal heat within five days of injection.

If corpora lutea are present on the ovary when the 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 product, wait 10 days before repeating the injection.

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

No specific treatment or antidote recommended.

4.11 Withdrawal period(s)

Meat: Zero days

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PG 600 is a freeze dried presentation of hCG and PMSG in combination with solvent for reconstitution. PG 600 contains 400iu of PMSG and 200iu 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, 27 and 36 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 PG600 efficiently induces and synchronizes puberty (gilts) and the first post weaning ovulation (sows).

ATCvet code: QG03GA99.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Disodium phosphate dihydrate
Sodium acid phosphate dehydrate

Diluent
Disodium phosphate dihydrate

Sodium acid phosphate dihydrate
Water for Injections

6.2 Incompatibilities

Do not mix this product with other medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 24 hours at 2-8°C.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

PG 600:
Freeze dried powder: Clourless Glass Type I (Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing a single dose or 5 doses.

Diluent: Colourless Glass Type I (Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing 5 ml or clear, colourless neutral Glass Type II (Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap, containing 25 ml diluent.

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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4095

9. DATE OF FIRST AUTHORISATION

27 July 1994

10. DATE OF REVISION OF TEXT

November 2024

Gavin Hall
Approved: 22 November 2024