

SPC

PG 600®



OTHER NAMES:
PG 600 SINGLE DOSE
SUIGONAN
PG 600 FIVE DOSES
PG 3000
SUIGONAN P5

ANNEX I

**SUMMARY OF
PRODUCT CHARACTERISTICS, LABELLING
AND PACKAGE LEAFLET**



CONTENTS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT	4
2. QUALITATIVE AND QUANTITATIVE COMPOSITION	4
3. PHARMACEUTICAL FORM.	4
4. CLINICAL PARTICULARS.	4
6. PHARMACEUTICAL PARTICULARS	7
7. MARKETING AUTHORISATION HOLDER	8
PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)	
CARTON BOX FOR SINGLE DOSE PRESENTATION.	11
PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)	
CARTON BOX FOR FIVE DOSES PRESENTATION	13
PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SMALL LABELS)	
PG600 FREEZE-DRIED POWDER SINGLE DOSE PRESENTATION (5 ML GLASS VIALS)	15
PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SMALL LABELS)	
PG600 FREEZE-DRIED POWDER FIVE DOSES PRESENTATION (10 ML GLASS VIALS)	16
PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SMALL LABELS)	
SOLVENT FOR RECONSTITUTION (5ML OR 25 ML)	17

1.A SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PG 600 (single dose presentation)

Also known as: PG 600 (one dose per vial)
PG 600 single dose
Suigonan

PG 600 (five dose presentation)

Also known as: PG 600 (five doses per vial)
PG 600 five dose vial
PG 3000
Suigonan P5

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

PG600 freeze-dried cake (single dose presentation):

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 200 I.U.

Gonadotrophin, equine serum (PMSG): 400 I.U.

PG600 freeze-dried cake (five dose presentation):

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 1000 I.U.

Gonadotrophin, equine serum (PMSG): 2000 I.U.

Solvent for reconstitution:

None

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for injection, supplied with reconstitution solvent.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (Sows and gilts)

4.2 Indications for use, specifying each target species

- Induction and synchronization of puberty in gilts.
- Induction and synchronization of the first ovulation post weaning (when administered on days 0 to 2 post weaning).
- Increasing litter size in subfertility (when administered on days 0 to 2 post weaning).
- Treatment of post weaning anoestrus (when injected 8 -12 days following weaning).
- Pregnancy diagnosis, administration within approximately 80 days post-service or A.I.

4.3 Contraindications

None known

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

None

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

Although the amounts of PMSG and hCG contained in PG 600 are limited, PMSG and hCG may modulate gonadal function in humans. Care must be taken when using PG 600 to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

The exposure of the user to the product is, however, minimized by the single injection therapeutic scheme.

Accidental spillage on the skin should be washed immediately with soap and water.

4.6 Adverse reactions (frequency and seriousness)

As with all protein-containing preparations, in rare cases, anaphylactoid-type reactions may occur shortly after administration. In such circumstances, prompt medication with adrenaline or glucocorticoids may be indicated.

Aseptic precautions should be adopted at the time of injection.

4.7 Use during pregnancy, lactation or lay

For pregnancy diagnosis

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 with the solvent provided, ensuring the powder plug is fully dissolved. Single dose vial of powder: reconstitute with 5 ml solvent supplied. Multidose vial of powder (5 doses): reconstitute with 25 ml solvent supplied. Make up immediately before use.

In gilts

- When oestrus induction and synchronization of 6-7 months old gilts weighing at least 85 kg, is required, inject one dose of PG 600 s.c./i.m. behind the ear.
- When puberty induction of gilts having failed to display puberty at 8-10 months of age is needed, inject one dose of PG 600 s.c./i.m. behind the ear.
- For pregnancy diagnosis, inject one dose of PG 600 s.c./i.m. behind the ear.

In sows

- To obtain induction and synchronization of the first post weaning ovulation, inject one dose of PG 600 s.c./i.m. behind the ear, between days 0 and 2 post weaning.
- To treat delayed return to oestrus in weaned sows, inject one dose of PG 600 s.c./i.m. behind the ear, between days 8 and 12 post weaning.
- To increase litter size in subfertility, inject one dose of PG 600 s.c./i.m. behind the ear, between days 0 and 2 post weaning.
- For pregnancy diagnosis, inject one dose of PG 600 s.c./i.m. behind the ear.

Oestrus normally appears 3-6 days after injection. Gilts/sows may then be inseminated or mated to boars.

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

None known.

4.11 Withdrawal period(s)

Meat and Offal:	0 days
Milk:	0 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones & modulators of the genital system
ATCvet code: QG03GA99.

5.1 Pharmacodynamic properties

PG 600 and PG3000 are freeze dried presentations 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).

5.2 Pharmacokinetic particulars

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 i.m. injection is high. In swine, the elimination half lives of PMSG and hCG were shown to be 36 and 27h respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

PG 600 freeze-dried cake (single dose and five doses presentations):

- Mannitol
- Disodium hydrogen phosphate dihydrate
- Sodium dihydrogen phosphate dihydrate
- Water for injections

Solvent for reconstitution:

- Disodium hydrogen phosphate dihydrate
- Sodium dihydrogen phosphate dihydrate
- Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

After reconstitution the product may be stored at 2 to 8°C for no longer than 24 hours.

6.4 Special precautions for storage

Store in a refrigerator (2-8°C)

6.5 Nature and composition of immediate packaging

PG600 freeze-dried cake (single dose presentation):

Freeze-dried cake of powder within a 5 ml colourless glass vial, closed with a halogenated butyl rubber stopper. The rubber stopper is held in place with an aluminium crimp cap.

PG600 freeze-dried cake (five doses presentation):

Freeze-dried cake of powder within a 10 ml colourless glass vial, closed with a halogenated butyl rubber stopper. The rubber stopper is held in place with an aluminium crimp cap.

Solvent for reconstitution:

Two presentations exist:

- 5ml of solvent supplied in a 5ml colourless, glass vial, closed with a halogenated butyl rubber stopper.
- 25ml of solvent supplied in a 30ml colourless glass vial, closed with a halogenated butyl rubber stopper.

All rubber stoppers are held in place with aluminium crimp caps.

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
The Netherlands

ANNEX II

PROPOSAL FOR LABELLING
AND PACKAGE LEAFLET



LABELLING



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)
CARTON BOX FOR SINGLE DOSE PRESENTATION****NAME OF THE VETERINARY MEDICINAL PRODUCT**

PG 600

STATEMENT OF ACTIVE AND OTHER SUBSTANCES**PG600 freeze-dried cake (single dose presentation):**

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 200 I.U.

Gonadotrophin, equine serum (PMSG): 400 I.U.

Solvent for reconstitution:

None

PHARMACEUTICAL FORM

Powder for injection, supplied with reconstitution solvent.

PACKAGE SIZE

Freeze-dried powder in a 5ml colourless glass vial and 5ml of solvent supplied in a 5ml colourless, glass vial, closed with a rubber stopper.

5 vials of freeze-dried powder and 5 vials of solvent per box.

Freeze-dried powder in a 5ml colourless glass vial and 5ml of solvent supplied in a 5ml colourless, glass vial, closed with a rubber stopper.

25 vials of freeze-dried powder and 25 vials of solvent per box.

TARGET SPECIES

Pigs (Sows and gilts)

INDICATION(S)

- Induction and synchronization of puberty in gilts.
- Induction and synchronization of the first ovulation post weaning (when administered on days 0 to 2 post weaning).
- Increasing litter size in subfertility (when administered on days 0 to 2 post weaning).
- Treatment of post weaning anoestrus (when injected 8 -12 days following weaning).
- Pregnancy diagnosis, administration within approximately 80 days post-service or A.I.

METHOD(S) AND ROUTE(S) OF ADMINISTRATION

After reconstitution of the product, inject s.c./i.m. behind the ear

WITHDRAWAL PERIOD

Milk & Meat: 0 days

SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Care must be taken when using PG 600 to avoid self-injection.

SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2-8°C)

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

READ THE PACKAGE LEAFLET BEFORE USE

Read the package leaflet before use.

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)
CARTON BOX FOR FIVE DOSES PRESENTATION****NAME OF THE VETERINARY MEDICINAL PRODUCT**

PG 600

STATEMENT OF ACTIVE AND OTHER SUBSTANCES**PG600 freeze-dried cake (five doses presentation):**

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 1000 I.U.

Gonadotrophin, equine serum (PMSG): 2000 I.U.

Solvent for reconstitution:

None

PHARMACEUTICAL FORM

Powder for injection, supplied with reconstitution solvent.

PACKAGE SIZE

Freeze-dried powder in a 10ml colourless glass vial and 25ml of solvent supplied in a 30ml colourless, glass vial, closed with a rubber stopper.

1 vial of freeze-dried powder and 1 vial of solvent per box.

Freeze-dried powder in a 10ml colourless glass vial and 25ml of solvent supplied in a 30ml colourless, glass vial, closed with a rubber stopper.

5 vials of freeze-dried powder and 5 vials of solvent per box.

TARGET SPECIES

Pigs (Sows and gilts)

INDICATION(S)

- Induction and synchronization of puberty in gilts.
- Induction and synchronization of the first ovulation post weaning (when administered on days 0 to 2 post weaning).
- Increasing litter size in subfertility (when administered on days 0 to 2 post weaning).
- Treatment of post weaning anoestrus (when injected 8 -12 days following weaning).
- Pregnancy diagnosis, administration within approximately 80 days post-service or A.I.

METHOD(S) AND ROUTE(S) OF ADMINISTRATION

After reconstitution of the product, inject s.c./i.m. behind the ear.

WITHDRAWAL PERIOD

Milk & Meat: 0 days

SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Care must be taken when using PG 600 to avoid self-injection.

SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2-8°C)

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

READ THE PACKAGE LEAFLET BEFORE USE

Read the package leaflet before use.

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

**PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SMALL LABELS)
PG600 FREEZE-DRIED POWDER SINGLE DOSE PRESENTATION (5 ML GLASS VIALS)****NAME OF THE VETERINARY MEDICINAL PRODUCT**

PG 600

QUANTITY OF THE ACTIVE SUBSTANCE(S)**PG600 freeze-dried cake (single dose presentation):**

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 200 I.U.

Gonadotrophin, equine serum (PMSG): 400 I.U.

ROUTE(S) OF ADMINISTRATION

After reconstitution of the product, inject s.c./i.m. behind the ear..

WITHDRAWAL PERIOD

Milk & Meat: 0 days

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

**PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SMALL LABELS)
PG600 FREEZE-DRIED POWDER FIVE DOSES PRESENTATION (10 ML GLASS VIALS)****NAME OF THE VETERINARY MEDICINAL PRODUCT**

PG 600

QUANTITY OF THE ACTIVE SUBSTANCE(S)**PG600 freeze-dried cake (five doses presentation):**

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 1000 I.U.

Gonadotrophin, equine serum (PMSG): 2000 I.U.

ROUTE(S) OF ADMINISTRATION

After reconstitution of the product, inject s.c./i.m. behind the ear.

WITHDRAWAL PERIOD

Milk & Meat: 0 days

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

**PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SMALL LABELS)
SOLVENT FOR RECONSTITUTION (5ML OR 25 ML)****NAME OF THE VETERINARY MEDICINAL PRODUCT**

SOLVENT FOR RECONSTITUTION

QUANTITY OF THE ACTIVE SUBSTANCE(S)

None

ROUTE(S) OF ADMINISTRATION

After reconstitution of the product, inject s.c./i.m. behind the ear.

WITHDRAWAL PERIOD

Milk & Meat: 0 days

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

PACKAGE LEAFLET



NAME OF THE VETERINARY MEDICINAL PRODUCT**PG 600 (single dose presentation):**

Also known as: PG 600 (one dose per vial)
PG 600 single dose
Suigonan

PG 600 (five dose presentation):

Also known as: PG 600 (five doses per vial)
PG 600 five dose vial
PG 3000
Suigonan P5

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**PG600 freeze-dried cake (single dose presentation):**

Per vial of freeze-dried powder for injection:
Gonadotrophin, chorionic (hCG): 200 I.U.
Gonadotrophin, equine serum (PMSG): 400 I.U.
Anhydrous freeze-dried excipients
PG600 freeze-dried cake (five dose presentation):

Per vial of freeze-dried powder for injection:

Gonadotrophin, chorionic (hCG): 1000 I.U.
Gonadotrophin, equine serum (PMSG): 2000 I.U.
Anhydrous freeze-dried excipients

Solvent for reconstitution:

Aqueous phosphate buffer

PHARMACEUTICAL FORM

Powder for injection, supplied with reconstitution solvent.

INDICATION(S)

- Induction and synchronization of puberty in gilts.
- Induction and synchronization of the first ovulation post weaning (when administered on days 0 to 2 post weaning).
- Increasing litter size in subfertility (when administered on days 0 to 2 post weaning).
- Treatment of post weaning anoestrus (when injected 8 -12 days following weaning).
- Pregnancy diagnosis, administration within approximately 80 days post-service or A.I.

CONTRAINDICATIONS

None known.

ADVERSE REACTIONS

As with all protein-containing preparations, in rare cases, anaphylactoid-type reactions may occur shortly after administration. In such circumstances, prompt medication with adrenaline or glucocorticoids may be indicated.

Aseptic precautions should be adopted at the time of injection.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Pigs (Sows and gilts)

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In gilts

- When oestrus induction and synchronization of 6-7 months old gilts weighing at least 85 kg, is required, inject one dose of PG 600 s.c./i.m. behind the ear.
- When puberty induction of gilts having failed to display puberty at 8-10 months of age is needed, inject one dose of PG 600 s.c./i.m. behind the ear.
- For pregnancy diagnosis, inject one dose of PG 600 s.c./i.m. behind the ear.

In sows

- To obtain induction and synchronization of the first post weaning ovulation, inject one dose of PG 600 s.c./i.m. behind the ear, between days 0 and 2 post weaning.
- To treat delayed return to oestrus in weaned sows, inject one dose of PG 600 s.c./i.m. behind the ear, between days 8 and 12 post weaning.
- To increase litter size in subfertility, inject one dose of PG 600 s.c./i.m. behind the ear, between days 0 and 2 post weaning.
- For pregnancy diagnosis, inject one dose of PG 600 s.c./i.m. behind the ear.

Oestrus normally appears 3-6 days after injection. Gilts/sows may then be inseminated or mated to boars.

WITHDRAWAL PERIOD

Meat and Offal:	0 days
Milk:	0 days

SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2-8°C).

After reconstitution the product may be stored at 2 to 8°C for no longer than 24 hours.

Keep out of the reach and sight of children.

SPECIAL WARNING(S)

Although the amounts of PMSG and hCG contained in PG 600 are limited, PMSG and hCG may modulate gonadal function in humans. Care must be taken when using PG 600 to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

The exposure of the user to the product is, however, minimized by the single injection therapeutic scheme.

Accidental spillage on the skin should be washed immediately with soap and water.

Do not use in pregnant animals.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

OTHER INFORMATION

For animal treatment only.

Product of Intervet International B.V., Boxmeer, The Netherlands