

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PG 600 Powder and Solvent for Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contents:

5 vials each containing:

SERUM GONADOTROPHIN 400 iu

CHORIONIC GONADOTROPHIN 200 iu

5 vials each containing: 5 ml sterile phosphate buffered water for injection.

1 vial PG 600 containing 5 doses:

Each dose contains:

SERUM GONADOTROPIN 400 iu

CHORIONIC GONADOTROPIN 200 iu

1 vial containing 25 ml sterile buffered solvent.

3. PHARMACEUTICAL FORM

Freeze dried powder for reconstitution with supplied solvent prior to use.

4. PACKAGE SIZE

5 vials with solvent

1 x 5 doses with solvent

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration to sows and gilts by intramuscular injection.

Read package leaflet for directions, disposal advice and warnings before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Meat – Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for directions, disposal advice and warnings before use.

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.

10. EXPIRY DATE

Expiry end of:

Exp end of:

Once broached use by:

11. SPECIAL STORAGE CONDITIONS

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.

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet for directions, disposal advice and warnings before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

FOR ANIMAL TREATMENT ONLY.

UK: POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Authorisation holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

Distributor in Northern Ireland:

Distributed in Northern Ireland by:

INTERVET IRELAND Ltd.

Magna Drive, Magna Business Park

Citywest Road, DUBLIN 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4312

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL LABEL (ACTIVE SUBSTANCE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PG 600 Powder and Solvent for Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

SERUM GONADOTROPHIN 400 iu AND CHORIONIC GONADOTROPHIN 200 iu
PER DOSE

3. PHARMACEUTICAL FORM

Powder and Solvent for Solution for Injection

4. PACKAGE SIZE

1 Dose

5 Doses

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M.

For administration to sows and gilts.

Read leaflet for directions and warnings before use.

8. WITHDRAWAL PERIOD

Withdrawal periods: Meat - Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read leaflet for directions and warnings before use.

Avoid accidental self-injection of this product.

10. EXPIRY DATE

Expiry end of:

Discard date:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (+2°C to +8°C).

Protect from light.

Keep container in outer carton.

This product does not contain a preservative.

Reconstituted product should be stored no longer than 24 hours at 2-8 °C.

Discard unused solution.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read leaflet for directions and warnings before use.

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MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4312

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

SOLVENT FOR PG 600 Powder and solvent for solution for injection

STERILE PHOSPHATE BUFFERED WATER FOR INJECTION

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

25 ml

3. ROUTES OF ADMINISTRATION

Read package leaflet for directions before use.

4. STORAGE CONDITIONS

Reconstituted product should be stored no longer than 24 hours at 2-8°C.

Store in a refrigerator (+2°C to +8°C).

Protect from light.

Keep container in outer carton

5. BATCH NUMBER

Batch No.:

6. EXPIRY DATE

Expiry end of:

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

KEEP OUT OF REACH OF CHILDREN

UK: POM-V

To be supplied only on veterinary prescription.

Authorisation holder:

MSD Animal Health UK Ltd.

Vm 01708/4312

PACKAGE LEAFLET FOR:

PG 600 POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PG 600 Powder and Solvent for Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

PRESENTATION

PG 600 is presented as a freeze dried white crystalline plug for reconstitution with solvent provided.

Each reconstituted 5 ml dose contains:

Serum gonadotrophin 400 iu

Chorionic gonadotrophin 200 iu

4. INDICATION(S)

USES

The action of serum gonadotrophin is similar to that of the follicle stimulating hormone (FSH) secreted by the anterior pituitary gland. In the same way chorionic gonadotrophin may be compared with luteinising hormone (LH).

The combination of gonadotrophins in PG 600 is indicated for the promotion of a fertile oestrous cycle in gilts and in sows post-weaning, and the treatment of suboestrus or anoestrus due to hormonal imbalance in barren sows.

5. CONTRAINDICATIONS

CONTRA-INDICATIONS, WARNINGS ETC

Do not inject into subcutaneous fat.

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

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.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

DOSAGE AND ADMINISTRATION

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.

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

Gilts: Administration of a single dose of PG 600 to non-cycling 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 should be given within 48 hours of weaning.

Anoestrus or acyclic sows: Cases of suboestrus or anoestrus due to hormonal imbalance may respond to a single dose of PG 600, exhibiting normal heat within five days of injection.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat - Zero days.

11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL PRECAUTIONS

Store in a refrigerator (+2°C to +8°C).

Protect from light.

Reconstituted solution should be stored for no longer than 24 hours at 2-8°C.

Discard unused solution.

This product does not contain a preservative.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on the package insert, the date on which any product remaining in the carton should be discarded should be written in the space provided.

Keep container in the outer carton.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

12. SPECIAL WARNING(S)

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DATE OF PREPARATION

December 2020

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH OF CHILDREN.

LEGAL CATEGORY

POM-V

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

5 x single dose vials with solvent; 5 dose vial with solvent.

FURTHER INFORMATION

The injection of PG 600 into a pregnant sow or gilt will fail to produce heat and will not cause abortion.

If corpora lutea are present on the ovary when PG 600 is administered, the sow or gilt will fail to respond. For this reason, if an anoestrus sow or gilt fails to respond to PG 600, wait 10 days before repeating the injection.

For the technique for intramuscular injection, refer to the Intervet injection technique literature.

MARKETING AUTHORISATION NUMBER

Vm 01708/4312

MA Holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Distributed in Northern Ireland by:

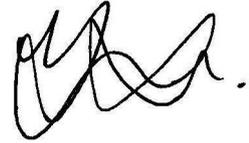
INTERVET IRELAND Ltd.
Magna Drive, Magna Business Park
Citywest Road
DUBLIN 24

Manufacturers responsible for batch release:

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

Or

Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 30 December 2020