PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PMSG-Intervet 5000iu powder and solvent for solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

SERUM GONADOTROPHIN 5000 iu

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

1 vial with solvent

This pack contains:

1 vial containing SERUM GONADOTROPHIN 5000 iu

1 vial containing 25 ml sterile buffered solvent.

5. TARGET SPECIES

Cattle, pigs, sheep and dogs

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration to cows, ewes, sows and bitches by i.m. or s.c. injection.

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

8. WITHDRAWAL PERIOD

Withdrawal periods:

General Indications

Milk (cattle)	Zero hours
Meat (cattle, pigs, sheep)	Zero days

Superovulation in cattle

Milk (cattle)	48 hours after 2nd prostaglandin treatment
Meat (cattle)	28 days

9. SPECIAL WARNING(S), IF NECESSARY

Avoid accidental self-injection of this product.

Wash hands after use.

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

10. EXPIRY DATE

Expiry:

Use reconstituted product within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2-8°C).

Protect from light.

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

POM-V

UK authorised veterinary medicinal product.

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

MA Holder:

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

Distributed in Northern Ireland by:

INTERVET IRELAND LTD.
Magna Drive
Magna Business Park
Citywest Road
DUBLIN 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4096

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (CONTAINING ACTIVE) LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PMSG-Intervet 5000iu powder and solvent for solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

SERUM GONADOTROPHIN 5000 iu

3. PHARMACEUTICAL FORM

Powder for solution for injection.

4. PACKAGE SIZE

5. TARGET SPECIES

Cattle, pigs, sheep and dogs

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M. + S.C.

For administration to cows, ewes, sows and bitches.

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

8. WITHDRAWAL PERIOD

Withdrawal periods:

General indications: Meat/Milk – zero days, Superovulation: Meat – 28 days, Milk 48 hours after 2nd prostaglandin treatment.

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.

Wash hands after use.

10. EXPIRY DATE

Exp end of

Use reconstituted product within 24 hours.

Use by:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2-8°C).

Protect from light.

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.

Discard unused solution.

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

[Distribution category]

FOR ANIMAL TREATMENT ONLY

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 AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4096

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

SOLVENT FOR PMSG-Intervet 5000iu powder and solvent for solution for injection

STERILE PHOSPHATE BUFFERED WATER FOR INJECTION

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

25 ml

3. ROUTES OF ADMINISTRATION

Read insert leaflet for directions before use.

4. STORAGE CONDITIONS

Store in a refrigerator (2-8°C)

Protect from light.

Keep container in outer carton

5. BATCH NUMBER

Batch No.:

6. EXPIRY DATE

Exp. End of:

Reconstituted product should be used within 24 hours.

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

Keep out of reach of children

POM-V

To be supplied only on veterinary prescription

Vm 06376/4096

UK authorised veterinary medicinal product.

MA Holder:

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

PACKAGE LEAFLET FOR:

PMSG-Intervet 5000 iu 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

Marketing Authorisation holder

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

Manufacturer for the batch release

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

or

Intervet International GmbH,
Feldstrasse 1a,
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PMSG Intervet 5000 iu powder and solvent for solution for injection

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

PMSG-Intervet 5000 iu powder and solvent for solution for injection is presented as a white, freeze-dried crystalline plug containing 5000 iu Serum Gonadotrophin (PMSG) supplied with a vial containing sterile aqueous solution for reconstitution, which

when reconstituted gives a solution containing 200 iu PMSG per ml.

4. INDICATION(S)

PMSG is capable of supplementing and being substituted for both luteinising hormone and follicle stimulating gonadotrophin of the anterior pituitary gland in both the male and female, stimulating development of the ovarian follicle.

5. CONTRAINDICATIONS

Where the possibility of multiple ovulations, due to exaggerated response from prolonged blood concentrations, has not been excluded by clinical examination following administration of PMSG to uniparous species (unless to induce superovulation in cattle), it is inadvisable to permit service or insemination during the first heat produced.

6. ADVERSE REACTIONS

In rare cases, as with all protein preparations, anaphylactoid incidents may occur shortly after injection. Adrenaline injection (1:1000) given intravenously or intramuscularly when clinical signs appear is the standard treatment. The administration of corticosteroids may also be indicated.

7. TARGET SPECIES

Cattle, pigs, sheep and dogs.

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

Make up immediately before use.

Reconstitute by dissolving the powder plug in about 5 ml of the solvent provided and then syringe the resulting solution into the solvent vial to mix with the remaining solvent.

Administer by subcutaneous or intramuscular injection using normal aseptic precautions.

Cow:

In conjunction with the use of progestagen treatment when used for oestrus control in noncycling

cattle:

400-700 iu (see also datasheet for progestagen treatment)

Superovulation:

1500-4000 iu - on day 9-13 of oestrous cycle

Sow:

Anoestrus post weaning (induction of oestrus is difficult until 40 days post partum):

1000 iu - s.c. or i.m. Fertile oestrus usually follows in 3 - 7 days

Ewe:

In conjunction with progestagen-releasing sponges when used out of the normal breeding season:

500 iu - s.c. or i.m. at time of sponge removal (see Further information)

Bitch:

Oestrus induction (subnormal oestrus with non-acceptance):

20 iu/kg - s.c. daily for 10 days, at day 10 injection of 500 iu hCG.

Superovulation in cattle

The product may be used for the superovulation of female donor cattle preparatory to embryo transfer. As an example, the following regime has been successfully applied:-

A single dose of the product (1500 - 4000 iu) is injected on day 9 - 13 of a normal oestrous cycle (NB the exact dose of the product required to achieve effective superovulation will depend upon a number of factors particularly the breed, age, reproductive history, general health and nutritional status of the donor female and will be subject to individual variation).

Forty-eight hours after the injection, luteolysis is induced by the injection of a prostaglandin analogue. Commonly one and a half times the normal luteolytic dose is administered.

Oestrus normally occurs approximately 48 hours after the prostaglandin injection.

Insemination is carried out at 60 and 72 hours after prostaglandin injection.

Collection of fertilised embryos (flushing) is carried out 6-8 days after insemination, suitable embryos being transferred to female recipient cattle whose oestrous cycles have previously been synchronised with that of the donor female.

(Experience has shown that oestrous cycles in donor and recipient females should be synchronised within ± 24 hours if reasonable success is to be expected). A further prostaglandin treatment (commonly 1½ times the luteolytic dose) must be given at the time of collection.

Note:

1 Despite the application of a suitable treatment regime certain individual donor cows may fail to respond.

2 Wide variations in response may be expected between individual animals. Repeated treatment of a single animal may also yield variable results.

3 The overall success of an embryo transfer exercise will inevitably be influenced by the availability of suitable equipment and the skill and experience of the operator.

Further information

PMSG has been used in cases of impaired spermatogenesis in male animals (horse & bull 1000-3000 iu, boar & ram 500-750 iu, dog 400-800 iu, i.m. twice weekly for 4-6 weeks), but its degree of efficacy in these cases may be low.

PMSG is a protein hormone which acts on the ovary to stimulate the production of follicles.

The number of follicles produced can be influenced by the dose of PMSG administered and this must be taken into account when, for instance, calculating the dose for a particular flock of ewes in which oestrus synchronisation is desired. In general, the further out of season that breeding is attempted and the lower the normal prolificacy of the flock, the more PMSG that will be required.

An average dose of 500 iu / ewe is recommended as a useful starting point but doses ranging from 200 - 750 iu have been used on occasion. It is therefore recommended that accurate flock records are kept of breed, dose given, time of injection and lambs produced so that in future seasons the amount can, if necessary, be adjusted for optimum results.

9. ADVICE ON CORRECT ADMINISTRATION

Care should be taken to avoid accidental self-injection.

Wash your hands after use.

10. WITHDRAWAL PERIOD(S)

Milk (Cattle): Zero days.

Meat (Cattle, pigs, sheep): Zero days

Superovulation in cattle

Milk: 48 hours after 2nd prostaglandin treatment

Meat: 28 days.

11. SPECIAL STORAGE PRECAUTIONS

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

Protect from light.

Reconstituted product should be stored in a refrigerator (2-8°C), and reconstituted product remaining 24 hours after preparation should be discarded.

Keep out of reach and sight of children.

12. SPECIAL WARNING(S)

Repeated administration can result in reduced efficacy due to the immune-mediated antagonism.

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

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

15. OTHER INFORMATION

For animal treatment only.

Clear, Glass Type I vials with halogenated butyl rubber stoppers with aluminium crimp caps (used by the Netherlands site) and clear, Glass Type I vials with bromobutyl rubber stoppers with aluminium crimp caps (used by the Germany site).

Colourless glass vial containing 25 ml solvent for reconstitution. Packaged in a carton containing 1 vial of powder and 1 vial of solvent.

Marketing Authorisation number: Vm 06376/4096

POM-V

To be supplied only on veterinary prescription.

Distributed in Northern Ireland by:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park, Citywest Road, Dublin 24

Gavin Hall

Approved: 22 November 2024