SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PMSG Intervet 5000 IU powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of freeze-dried powder contains:

Active substance:
Serum gonadotrophin 5000 IU

Excipients:

Qualitative composition of excipients and other constituents
Mannitol
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate

Each vial of solvent contains:

Excipients:

Qualitative composition of excipients and other constituents
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Water for injections

Each ml of reconstituted product contains:

Active substance:
Serum gonadotrophin 200 IU

Excipients:

Qualitative composition of excipients and other constituents
Mannitol
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Water for injections

Powder: white to almost white, dry lump or powder.
Solvent: clear colourless solution, practically free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, sheep and dogs.

3.2 Indications for use for each target species

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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Repeated administration can result in reduced efficacy due to the immune-mediated antagonism.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Administer the veterinary medicinal product with care to avoid accidental self-injection. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, pigs, sheep and dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylaxis[1].

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use or intramuscular use. Use normal aseptic precautions.
Reconstitute product 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 to obtain a clear, colourless solution.

Cow:
In conjunction with the use of progestagen treatment when used for oestrus control in non-cycling cattle:
400 - 700 IU.

Superovulation:
1500 - 4000 IU on day 9 - 13 of the oestrous cycle.

Sow:
Anoestrus post weaning (induction of oestrus is difficult until 40 days post-partum):
1000 IU by subcutaneous or intramuscular injection. 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 by subcutaneous or intramuscular injection at the time of sponge removal.

Bitch:
Oestrus induction (subnormal oestrus with non-acceptance):
20 IU/kg by subcutaneous injection daily for 10 days, at day 10 an 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 (N.B. 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 and bull 1000 - 3000 IU, boar and ram 500 - 750 IU, dog 400 - 800 IU, by intramuscular injection 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 considered 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**.**

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No special treatment or antidote recommended.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Milk (Cattle): Zero days
Meat and offal (Cattle, pigs, sheep): Zero days

Superovulation in cattle
Milk: 48 hours after 2nd prostaglandin treatment
Meat and offal: 28 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03GA03.

4.2 Pharmacodynamics

PMSG is a potent gonadotrophin, with dual FSH and LH activity. It is composed of two non-covalently associated alpha and beta subunits and is heavily glycosylated on its CTP tail. This extensive glycosylation is of key importance for obtaining the extended half-life in blood typical of PMSG. As PMSG binds to FSH and LH receptors, it stimulates follicular growth and follicular maturation during the days preceding oestrus and ovulation. Limited amounts of PMSG will result in induction and synchronization of ovulation in cattle and small ruminants, irrespective of their cyclicity prior to treatment. Administration of slightly higher amounts will modestly increase ovulation rate and litter size. Administration of high amounts of PMSG will result in superovulation, therefore resulting in the numerous blastocysts needed for embryo transfer. PMSG also has the potential to induce puberty in swine.

4.3 Pharmacokinetics

The pharmacokinetic profile observed following injection of PMSG is characterised by the very long half-life generated by the high glycosylation (N and O glycosylations) of the PMSG molecule. It also explains why a single PMSG administration has the ability to support follicular growth throughout the full duration of the follicular phase (2 to 5 days long according to the species).
Absorption of PMSG is rapid: In all three species studied, following injection, PMSG is rapidly absorbed from the injection site and C max is reached by 8 hours (pig/sheep) or 16 hours (cattle) following injection. Bioavailability following intramuscular injection (compared to intravenous administration) is high in all species (cattle: 72%, pig: 71.3%, sheep: 92.6%).
PMSG elimination is slow: The elimination half-life has been shown to range between 34 and 150 hours according to the species.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Keep the vials in the outer carton in order to protect from light.
Store reconstituted product in a refrigerator (2 °C – 8 °C).
Reconstituted product remaining 24 hours after preparation should be discarded.

5.4 Nature and composition of immediate packaging

Powder: 5 ml colourless type I glass vial, closed with a bromobutyl rubber stopper, and secured with an aluminium crimp cap.
Solvent: 25 ml colourless type II glass vial, closed with a bromobutyl rubber stopper, and secured with an aluminium crimp cap.
Pack size: Cardboard box containing one vial of powder and one vial of solvent.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4096

8. DATE OF FIRST AUTHORISATION

03 August 1994

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 15 October 2025

Gavin Hall