1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STIMOVAR INJECTION lyophilisate and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This product is available in two pack sizes.

7500 IU pack size
Each vial of lyophilisate contains:

Active substances:
Equine Serum Gonadotrophin …… 7500 IU

Each 1 ml of reconstituted product contains 375 IU of Equine Serum Gonadotrophin.

1000 IU pack size
Each vial of lyophilisate contains:

Active substances:
Equine Serum Gonadotrophin …… 1000 IU

Each 1 ml of reconstituted product contains 50 IU of Equine Serum Gonadotrophin

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate
Lactose
Mannitol
Solvent
Sodium Chloride
Potassium dihydrogen Orthophosphate
Disodium Hydrogen Orthophosphate
Purified Water

Lyophilisate powder: White powder.
Solvent: Limpid and colourless solution free of foreign particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, Sheep, Goats, Pigs and Dogs.

3.2 Indications for use for each target species

Pregnant mares serum gonadotrophin (PMSG) is used as an aid to increase reproductive efficiency in livestock. It will induce oestrus in anoestrus animals and increase ovulation rate when used in conjunction with an appropriate progestogen pre-treatment. The ovulation rate increases with increasing dose level and causes super ovulation at higher levels.

Sheep & Goats: Oestrus induction and increased ovulation. Super-ovulation.

Cattle: Anoestrus. Super-ovulation.

Dogs: Anoestrus.

Pigs: Anoestrus. Lactational anoestrous. Prolonged weaning to mating interval.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Normal aseptic precautions should be observed during reconstitution and injection of the product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care must be taken to avoid accidental self-injection.

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

3.6 Adverse events

Cattle, Sheep, Goats, Pigs and Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Anaphylactic reaction[1]

[1]Most cases recover eventually but affected animals can be treated with intramuscular or intravenous adrenaline.

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:
Do not use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

It is not recommended to administer anthelmintics or vaccines to animals at the time of injecting PMSG.

3.9 Administration routes and dosage

Administration route: intramuscular or subcutaneous use.

Reconstituted product: Limpid and colourless free of foreign particles.

Recommended Dosage Schedules:

Species	Indication	Dosage
Sheep & Goats	Oestrus induction and increased ovulation. Super-ovulation	Injection of 300-750 IU veterinary medicinal product at time of cessation of treatment with a progestogen. Injection of 500-1500 IU veterinary medicinal product 36-48 hours before cessation of treatment with a progestogen or injection of a prostaglandin.
Cattle	Anoestrus. Super-ovulation.	500-1000 IU veterinary medicinal product. 1500-3000 IU ovulation veterinary medicinal product on day 8-13 of the oestrus cycle followed 48 hours later by injection of prostaglandin. Injection of 100-500 IU veterinary medicinal product per kg bodyweight at 7-day intervals until oestrus occurs.
Dogs	Anoestrus.	Injection of 500-1000IU I.V. Human Chorionic Gonadotrophin (HCG) on day 4 of oestrus. or: Daily injections of 20 IU veterinary medicinal product per kg bodyweight over 10 days. Injection of 500-1000 IU S.C. HCG on day 10.
Pigs	Anoestrus.	Injection of 500-1000 IU veterinary medicinal product to gilts or sows.
	Lactational anoestrous.	Injection of 1000-2000 IU veterinary medicinal product 10 or more days after farrowing followed 3-4 days later by injection of 500-1000 IU HCG.
	Prolonged weaning to mating interval.	Injection 500-1000 IU veterinary medicinal product at weaning.

Administration should be restricted to the anterior half of the neck.
The dose depends on the breed, age and season.

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

Overdosage, at 10 times the recommended dose can result in a rise in body temperature and to superovulation and consequently lower fertility due to increased oestrogen in the reproductive environment.

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

Meat and offal: 10 days.
Milk: 24 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG03GA03

4.2 Pharmacodynamics

Pregnant mares serum gonadotrophin (PMSG) has been used extensively in research and commercial animal protection for over 40 years. Its ability to stimulate ovulation and increase ovulation rates in farm animals is well documented. PMSG appears to act through the prevention of atresia of antral follicles or recruitment of follicles by acceleration of growth or both.

4.3 Pharmacokinetics

There are a number of reports that detail the half life of PMSG in various species:
Sheep: 21 hours (McIntosh et al 1975).
Cattle: 50 - 120 hours (Schains et al 1978).
Rats: 26 hours (Parlow and Ward, 1961).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except diluent supplied for use with the product.

5.2 Shelf life

The recommended shelf life in lyophilised powder form is 3 years.
The recommended shelf life for the diluent is 3 years.

Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 ºC – 8 ºC).

5.4 Nature and composition of immediate packaging

Lyophilised: clear 10 ml glass vial, Type II sealed with a butyl rubber stopper.

Solvent: clear 20 ml glass vial, Type II sealed with a butyl rubber stopper.

Pack sizes:
Cardboard box with 1 vial of lyophilizate (7500 IU) and 1 vial of solvent (20 ml).
Cardboard box with 1 vial of lyophilizate (1000 IU) and 1 vial of solvent (20 ml).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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

LABORATORIOS OVEJERO S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10396/002/001

8. DATE OF FIRST AUTHORISATION

15/06/1993

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

15/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).