1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STIMOVAR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This product is available in two pack sizes, one containing 7500 iu and the other 1000 iu

7500 iu Pack size
Active substance
Equine Serum Gonadotrophin 7500 IU
Diluent
Phosphate buffered saline 20 ml
1 ml of reconstituted product contains 375 IU Equine Serum Gonadotrophin

1000 iu Pack size
Active substance
Equine Serum Gonadotrophin 1000 IU
Diluent
Phosphate buffered saline 20 ml
1 ml of reconstituted product contains 50 IU Equine Serum Gonadotrophin

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM
Powder and solvent for solution for injection.

4. CLINICAL PARTICULARS
4.1 Target species
Cattle, Sheep, Goats, Pigs and Dogs

4.2 Indications for use, specifying the target species
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.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

In rare cases an anaphylactic reaction may occur after injection. Most cases recover eventually but affected animals can be treated with intramuscular or intravenous adrenaline.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy

4.8 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.

4.9 Amounts to be administered and administration route

PMSG can be administered by intramuscular or subcutaneous injection. Administration should be restricted to the anterior half of the neck. The dose depends on the breed, age and season.

Recommended Dosage Schedules:

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

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

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.

4.11 Withdrawal period(s)

Meat and offal: 10 days.

Milk: 24 hours following the last treatment.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genito urinary system and sex hormones, gonadotrophins and other ovulation stimulants, serum gonadotrophin.

ATC vet code: QG03GA03

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.

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)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Mannitol

Solvent:
Disodium Hydrogen Orthophosphate
Potassium dihydrogen Orthophosphate
Sodium Chloride
Purified Water

6.2 Incompatibilities

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

6.3 Shelf life

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

The recommended shelf life for the diluent is 3years.

It is recommended to use the product immediately after reconstitution and to discard any material unused after reconstitution.

6.4. Special precautions for storage

Store in a refrigerator at+2 to +8ºC.

6.5 Nature and composition of immediate packaging

The PMSG Stimovar is contained in a clear 10 ml glass vial. Type II sealed with a butyl rubber stopper. The sterile diluent is contained in a clear 20 ml glass vial. Type II sealed with a butyl rubber stopper. Both Stimovar and sterile diluent are presented in a cardboard box, with instructions for use printed on the outside. Each pack contains an information leaflet on the use of the product. Not all pack sizes may be marketed.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Ovejero S.A.

8. MARKETING AUTHORISATION NUMBER(S)

VPA10396/002/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/06/1993

10. DATE OF REVISION OF THE TEXT

15/03/2024