SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CUNISER 500
Pregnant Mare Serum Gonadotrophin (PMSG) in powder and solvent for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Pregnant Mare Serum Gonadotrophin (PMSG) ..... 500 IU

For a full list of excipients, see section 6.1.

Solvent:
20 ml of phosphate buffer solution (PBS)
Ingredients: Potassium dihydrogen phosphate, disodium phosphate dodecahydrate, sodium chloride, potassium chloride and water for injectable preparations.

Each vial of lyophilisatedpowder is dissolved in the proper volume of solvent for reconstitution (20 ml). The final concentration of PMSG is 25 IU/ml

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits: Female rabbit for reproduction.

4.2 Indications for use, specifying the target species

Rabbits: Female rabbit for reproduction: induction and synchronisation of heat.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.
Do not administer to female rabbits for reproduction with polycystic ovaries.

4.4 Special warnings <for each target species>

Adjust the dosage. A higher dose of PMSG does not entail an increase in the efficacy of the veterinary medicinal product.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Should administer the veterinary medicinal product with caution.
In the event of contact with eyes or skin, wash with abundant water for several minutes.
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
The symptomatic treatment of the animals must be carried out by a veterinarian.

4.6 Adverse reactions (frequency and seriousness)

In rare cases may appear rashes or anaphylactic shock shortly after the injection of habitual doses in sensitive animals. In such case, administer an adrenalin injection or corticoids by intravenous or intramuscular route when the first symptoms appear.

4.7 Use during pregnancy, lactation or lay

Do not use during the whole pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administration route: intramuscular or subcutaneous.

Administer 25 IU per female rabbit for reproduction: equivalent to 1 ml of the reconstituted product per female rabbit for reproduction.
Administer 48 hours before natural mating or artificial insemination.
The medicine should be reconstituted using the entire quantity of solvent accompanying it (20 ml of PBS).
Dissolve the lyophilisatedpowder in a small quantity of solvent. Mix until a homogenous solution is obtained. Introduce this solution into a vial containing the rest of the solvent and mix until completely dissolved. The final concentration of PMSG is 25 IU/ml.

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

No adverse reactions occurred when a dose of 125 IU (5 times the recommended dose) was administered.

Higher doses of PMSG do not increase the efficacy of the product.

An overdose may give rise to superovulations and/or gestations with an elevated number of young. This implies an increase in the embryonary and neonatal mortality rate. It may also, over time, cause the synthesis of anti-PMSG antibodies.

An excessive concentration of PMSG would prolong the presence of antrum and/or pre-ovulatory follicles that could lead to ovaric cysts.

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotrophins and other ovulation stimulants.
ATCvet code: QG03GA03

Pregnant mare serum gonadotrophin (PMSG) is a glycoprotein that forms in the endometrial cups of the uterus of pregnant mares and is obtained directly from the serum or plasma of those animals.

5.1 Pharmacodynamic properties

PMSG's physiological activity is similar to follicle stimulating hormone (FSH), although it also shows certain activity typical of luteinising hormone (LH); these follicle and luteinising properties are responsible for its pharmacological activity.

PMSG stimulates the increase in the number and proliferation of follicles. It likewise stimulates the growth and maturation of the ovarian follicles and the formation of corpora lutea. This leads to a greater production of estrogens and the consequent accentuation of the sexual behaviour of the female rabbit for reproduction treated.

5.2 Pharmacokinetic particulars

When PMSG is administered by oral route it is destroyed by gastrointestinal tract enzymes. Therefore, it is only effective after being administered by parenteral route.

After intramuscular or subcutaneous administration, the absorption of PMSG reaches maximum serum concentrations between 12 and 24 hours post-administration.

This hormone follows a bicompartimental model with rapid distribution and a slow elimination phase.

PMSG metabolises at a hepatic level by the same metabolic routes as proteins and carbohydrates. Sialic acid must be eliminated from the PMSG so that the molecule can interact with membranes of the hepatic cells and be metabolised in them.

The average half life of elimination is slow (40-125 hours). PMSG has a long time of activity, in that it does not undergo glomerular filtration and so remains for a long time in systemic circulation in the treated animal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Mannitol
Povidone
Simethicone
Water for injectable preparations

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years..
Shelf-life after dilution or reconstitution according to directions: Use immediately.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

6.5 Nature and composition of immediate packaging

The lyophilisated powder is contained in:
- Type I 10 ml colourless glass vials, sealed with elastomer closures and aluminium caps flip-off, in a cardboard box.

The solvent is contained in:
- Type I 20 ml colourless glass vials that contain 20 ml of solvent in a cardboard box.

Presentations:

Unitary pack size:
1 cardboard box with 1 vial of CUNISER 500 (lyophilisate fraction)
1 cardboard box with 1 vial of diluent for CUNISER 500 (phosphate buffer solution, PBS)
Clinical pack size:
1 cardboard box containing 10 vials of CUNISER 500 (lyophilisate fraction)
1 cardboard box containing 10 vials of diluent for CUNISER 500 (phosphate buffer solution, PBS)

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170-AMER (Girona) Spain
Tel: 972 43 06 60
Fax: 972 43 06 61

8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only – to be supplied only on veterinary prescription.