

B. PACKAGE LEAFLET

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CUNISER 500

Pregnant Mare Serum Gonadotrophin (PMSG), in 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

LABORATORIOS HIPRA, S.A.
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17170 – AMER (GIRONA) SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

CUNISER 500 is a white lyophilised powder containing 500 IU of Pregnant Mare Serum Gonadotrophin (PMSG).

Excipients: Potassium dihydrogen phosphate, disodium phosphate dodecahydrate, mannitol, povidone, simethicone.

Solvent: 20 ml PBS. Colourless, transparent, liquid.

4. INDICATION(S)

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

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 doe rabbit treated.

5. 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.

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Rabbits: Female rabbit for reproduction.

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

This veterinary medicinal product should always be administered in conjunction with the solvent for CUNISER 500.

Subcutaneous or intramuscular route.

Dissolve the lyophilised powder in a small quantity of solvent. Mix until a homogenous solution is obtained. Introduce this solution in a vial containing the rest of the solvent and mix until completely dissolved. The final concentration of PMSG is 25 IU/ml.

Rabbits: female rabbit for reproduction: Administer 1 ml/female rabbit for reproduction (equivalent to 25 IU per female rabbit for reproduction).

Administer a single dose 48 hours before natural mating or artificial insemination.

9. ADVICE ON CORRECT ADMINISTRATION

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 ovarian cysts.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in a refrigerator (2 °C – 8 °C)

Use immediately after reconstitution.

Do not use after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

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

Should administer the veterinary medicinal product with caution.

Do not use during the whole pregnancy.

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.

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

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

PRESENTATIONS:

Unitary pack size:

1 cardboard box with 1 vial of CUNISER 500

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

1 cardboard box containing 10 vials of diluent for CUNISER 500 (phosphate buffer solution, PBS)

Not all pack sizes may be marketed.

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