[Version 7.3.2, 10/2011]

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CUNISER 1000
Pregnant Mare Serum Gonadotrophin (PMSG) in lyophilisated powder and solvent for injectable solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance :
Pregnant Mare Serum Gonadotrophin (PMSG) ..... 1000 IU

For a full list of excipients, see section 6.1.

Solvent:
40 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 lyophilisated powder is dissolved in the proper volume of solvent for reconstitution (40 ml). The final concentration of PMSG is 25 IU/ml

3. PHARMACEUTICAL FORM

Lyophilisated powder and solvent for injectable solution.

4. CLINICAL PARTICULARS

4.1 Target species

Doe rabbits.

4.2 Indications for use,specifying the target species

Doe rabbits: induction and synchronisation of heat.

4.3 Contraindications

Do not use in animals that have been demonstrated to be hypersensitive to gonadotrophins.
Do not administer to doe rabbits with polycystic ovaries.

4.4 Special warnings <for each target species>

None.

4.5 Special precautions for use

Special precautions for use in animals
Adjust the dosage. A higher dose of PMSG does not entail an increase in the efficacy of the veterinary medicinal product.

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)

Undesirable effects may sporadically appear such as 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 administer to gestating females.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route.

Administer 25 IU per doe rabbit: equivalent to 1 ml of the reconstituted product per doe rabbit.
Administer 48 hours before natural mating or artificial insemination.
CUNISER 1000 should be reconstituted using the entire quantity of solvent accompanying it (40 ml of PBS).
Dissolve the lyophilisated powder 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.
Administration route: intramuscular or subcutaneous.

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

Its 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 doe rabbit 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 after date of manufacture.
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 II 50 ml colourless glass vials that contain 40 ml of solvent in a cardboard box.

Presentations:

Unitary pack size:
1 cardboard box with 1 vial of CUNISER 1000 (lyophilisate fraction)
1 cardboard box with 1 vial of diluent for CUNISER 1000 (phosphate buffer solution, PBS)
Clinical pack size:
1 cardboard box containing 10 vials of CUNISER 1000 (lyophilisate fraction)
1 cardboard box containing 10 vials of diluent for CUNISER 1000 (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

BIOGÉNESIS GLOBAL S.L.
Quintanadueñas, 6, Bloque A, 1º piso
28050 Madrid- España
Tel.: +34 91 746 73 67

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.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LYOPHILISATE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CUNISER 1000
Pregnant Mare Serum Gonadotrophin (PMSG), in lyophilisated powder for injectable solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per vial:
Pregnant Mare Serum Gonadotrophin (PMSG) ..... 1000 IU

3. PHARMACEUTICAL FORM

Lyophilisated powder for injectable solution.

4. PACKAGE SIZE

Lyophilisated powder: 1000 IU per vial.

Each vial of lyophilisated powder is dissolved in the proper volume of solvent for reconstitution (40 ml). The final concentration of PMSG is 25 IU/ml.

5. TARGET SPECIES

Doe rabbits.

6. INDICATION(S)

Induction and synchronisation of heat.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

This veterinary medicinal product should always be administered in conjunction with the solvent for CUNISER 1000.
Dissolve the powder with the solvent.
Administer 1 ml/rabbit (equivalent to 25 IU per rabbit) by subcutaneous or intramuscular route.
Administer a single dose 48 hours before natural mating or artificial insemination.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL S.L.
Quintanadueñas, 6, Bloque A, 1º piso
28050 Madrid- España
Tel.: +34 91 746 73 67

16. MARKETING AUTHORISATION NUMBER(S)

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17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

DILUENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DILUENT FOR CUNISER 1000
Solvent for injectable solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per vial:
Phosphate buffer solution (PBS) .....40 ml

3. PHARMACEUTICAL FORM

Solvent for injectable solution.

4. PACKAGE SIZE

40 ml vial.

5. TARGET SPECIES

Doe rabbits.

6. INDICATION(S)

Induction and synchronisation of heat.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

This solvent should always be administered with the product CUNISER 1000.
Dissolve the powder with the solvent.
Administer 1 ml/rabbit (equivalent to 25 IU per rabbit) by subcutaneous or intramuscular route.
Administer a single dose 48 hours before natural mating or artificial insemination.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet enclosed in CUNISER 1000 before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL S.L.
Quintanadueñas, 6, Bloque A, 1º piso
28050 Madrid- España
Tel.: +34 91 746 73 67

16. MARKETING AUTHORISATION NUMBER(S)

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17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LYOPHILISATED POWDER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CUNISER 1000
Pregnant Mare Serum Gonadotrophin (PMSG), in lyophilisated powder for injectable solution.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition per vial:
Pregnant Mare Serum Gonadotrophin (PMSG) .....1000 IU

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 IU per vial

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular route.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Use immediately after reconstitution.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

DILUENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DILUENT FOR CUNISER 1000
Solvent for injectable solution

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Phosphate buffer solution (PBS)
40 ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

40 ml

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular route.
Read the package leaflet enclosed in CUNISER 1000 before use.

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
CUNISER 1000
Pregnant Mare Serum Gonadotrophin (PMSG), in lyophilisated powder and solvent for injectable solution

1.1 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL S.L.
Quintanadueñas, 6, Bloque A, 1º piso
28050 Madrid- España
Tel.: +34 91 746 73 67

1.2 RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 – AMER (GIRONA) SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CUNISER 1000
Pregnant Mare Serum Gonadotrophin (PMSG), in lyophilisated powder and solvent for injectable solution.

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

CUNISER 1000 is a white lyophilisated powder containing 1000 IU of Pregnant Mare Serum Gonadotrophin (PMSG).
Excipients: Potassium dihydrogen phosphate, disodium phosphate dodecahydrate, mannitol, povidone, simethicone.

Solvent: 40 ml PBS. Colourless, transparent, liquid.

4. INDICATION(S)

Doe rabbits: 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 animals that have been demonstrated to be hypersensitive to gonadotrophins.
Do not administer to does with polycystic ovaries.

6. ADVERSE REACTIONS

Undesirable effects may sporadically appear such as 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

Doe rabbit.

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 1000.
Subcutaneous or intramuscular route.
Dissolve the lyophilisated 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.
Doe rabbit: Administer 1 ml/rabbit (equivalent to 25 IU per rabbit).
Administer a single dose 48 hours before natural mating or artificial insemination.

9. ADVICE ON CORRECT ADMINISTRATION

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

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)

Should administer the veterinary medicinal product with caution.
Do not administer to gestating females.
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

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15. OTHER INFORMATION

PRESENTATIONS:
Unitary pack size:
1 cardboard box with 1 vial of CUNISER 1000
1 cardboard box with 1 vial of diluent for CUNISER 1000 (phosphate buffer solution, PBS)

Clinical pack size:
1 cardboard box containing 10 vials of CUNISER 1000
1 cardboard box containing 10 vials of diluent for CUNISER 1000 (phosphate buffer solution, PBS)

Not all pack sizes may be marketed.

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