

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**LYOPHILISATED POWDER****1. NAME OF THE VETERINARY MEDICINAL PRODUCT****CUNISER 1000**

Pregnant Mare Serum Gonadotrophin (PMSG), in powder for solution for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCESComposition per vial:

Pregnant Mare Serum Gonadotrophin (PMSG) 1000 IU

3. PHARMACEUTICAL FORM

Powder for solution for injection.

4. PACKAGE SIZE

Lyophilised powder: 1000 IU per vial.

Each vial of lyophilised 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

Rabbits: Female rabbit for reproduction.

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/female rabbit for reproduction (equivalent to 25 IU per female rabbit for reproduction) 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

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

16. MARKETING AUTHORISATION NUMBER(S)

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 solution for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per vial:

Phosphate buffer solution (PBS)40 ml

3. PHARMACEUTICAL FORM

Solvent for solution for injection.

4. PACKAGE SIZE

40 ml vial.

5. TARGET SPECIES

Rabbits: Female rabbit for reproduction.

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/female rabbit for reproduction (equivalent to 25 IU per female rabbit for reproduction) 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

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

16. MARKETING AUTHORISATION NUMBER(S)

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 powder for solution for injection.

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 solution for injection.

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.