

ANNEX III
LABELLING AND PACKAGE LEAFLET

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A. LABELLING

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PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 5 vials of lyophilisate and 1 vial of 10 ml solvent
Cardboard box containing 10 vials of lyophilisate and 2 vials of 10 ml solvent
Cardboard box containing 25 vials of lyophilisate and 1 vial of 50 ml solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncrostim 500 IU lyophilisate and solvent for solution for injection for cattle and sheep
equine serum gonadotrophin (eCG)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lyophilisate vial contains: eCG 500 IU
2 ml dose contains 500 IU eCG.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection

4. PACKAGE SIZE

Lyophilisate 5 vials - 10 ml solvent (5 doses)
Lyophilisate 10 vials - 2x10 ml solvent (10 doses)
Lyophilisate 25 vials - 50 ml solvent (25 doses)

5. TARGET SPECIES

Cattle, Sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

8. WITHDRAWAL PERIOD

Meat, offal and milk: zero days

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9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women should not handle the product.
Read the package leaflet before use and disposal.

10. EXPIRY DATE

EXP:
Once reconstituted, use immediately.
Shelf-life after first opening the solvent vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Lyophilisate vial: Protect from light and store in a refrigerator.

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

Read the package leaflet before use and disposal.

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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and address}

16. MARKETING AUTHORISATION NUMBER(S)

xxxx

17. MANUFACTURER’S BATCH NUMBER

Lot:

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PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE

Label of lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncrostim 500 IU
eCG

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1 dose of 500 IU eCG

4. ROUTE(S) OF ADMINISTRATION

I.M.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE

Label of 10 ml solvent vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncrostim 500 IU solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

10 ml

50 ml

4. ROUTE(S) OF ADMINISTRATION

I.M.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

Once broached, use by: ___/___/___

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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B. PACKAGE LEAFLET

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PACKAGE LEAFLET FOR

Syncrostim 500 IU, lyophilisate and solvent for solution for injection for cattle and sheep

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
{Name and address}

Manufacturer for the batch release:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncrostim 500 IU, lyophilisate and solvent for solution for injection for cattle and sheep
Equine serum Gonadotrophin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Lyophilisate vials contains:

Active substance:

Equine serum Gonadotrophin (eCG, formerly known as PMSG)..... 500 IU

Solvent vial contains:

Benzyl alcohol (E 1519)..... 16.5 mg /ml

Reconstituted solution for 1 dose of 2 ml contains:

Active substances

Equine serum Gonadotrophin (eCG, formerly known as PMSG) 500 IU

Excipients

Benzyl alcohol (E 1519) 33.0 mg

4. INDICATIONS

In non cycling cattle (cows and heifers) and in ewes and ewe-lambs:
Induction and synchronization of oestrus and ovulation. To be used in combination with a progestagen.

5. CONTRAINDICATIONS

See section “Use during pregnancy, lactation or lay”

6. ADVERSE REACTIONS

eCG is an exogenous protein for species other than equine. Therefore, antigen-antibody reactions may result. In very rare cases, repeated administrations of eCG can provoke anaphylactic shock (see section Special Warnings).

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

The frequency of adverse reactions is defined using the following convention:

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- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

7. TARGET SPECIES

Cattle, Sheep

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

Intramuscular use.

500 IU of equine serum gonadotrophin (eCG) per animal in one administration corresponding to 2 ml of the reconstituted solution.

The product should be administered at the time of the progestagen device withdrawal.

9. ADVICE ON CORRECT ADMINISTRATION

Dissolve the lyophilisate with 2 ml of solvent. Mix until completely dissolved to obtain a homogenous solution. The reconstituted solution should be used immediately.

10. WITHDRAWAL PERIOD

Meat, offal and milk: zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C - 8°C).

Lyophilisate: protect from light.

Shelf-life after first opening the vial of solvent: 28 days.

Shelf life after reconstitution according to directions: use immediately.

Do not use after the expiry date stated on the carton and vial after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species

Especially in ovine, dosing of eCG should be adapted to the breed (doses should be lower in prolific breeds) and to the reproductive season of animals (higher when used off season).

User warnings

Care should be taken when handling the product to avoid self-injection. In case of accidental self-injection, seek medical advice, and show the package leaflet.

Wash hands after handling the product.

Studies in laboratory animals exhibited teratogenic effects after the administration of eCG. Pregnant women, those intending to become pregnant, or whose pregnancy status is unknown, should not handle the product.

Accidental spillage on the skin should be washed off immediately with soap and water.

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Special precautions for use in animals

In case of anaphylactic shock, symptomatic treatment (e.g. adrenaline or corticosteroids) should be administered.

Use during pregnancy, lactation or lay

Studies in laboratory animals have shown teratogenic effects after administration of eCG.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy

Interactions

None known.

Overdose

Administration of higher doses than recommended doses may increase the risk of twins in cattle and triplets in sheep.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{month/year}

15. OTHER INFORMATION

Pack sizes:

Cardboard box containing 5 vials of lyophilisate and one vial of 10 ml solvent

Cardboard box containing 10 vials of lyophilisate and 2 vials of 10 ml solvent

Cardboard box containing 25 vials of lyophilisate and one vial of 50 ml solvent

Not all pack sizes may be marketed.

Pharmacodynamic properties

Equine Serum Gonadotrophin (eCG, in the past called PMSG) is a large glycoprotein secreted during pregnancy in the mare and its structure is similar to the endogenous gonadotrophin hormones: FSH and LH.

eCG exerts its effects on FSH and LH receptors of target cells distributed in the gonads: in females, eCG supports the ovarian follicular maturation by stimulating the growth and development of antral follicles. In ovine and in non-cycling bovine female, its use is recommended after a treatment for the synchronization of œstrus with a progestagen: eCG improves follicle maturation and ovulation rate and allows synchronization of ovulation.

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Pharmacokinetic particulars

In plasma, eCG declines biphasically with species terminal half-lives of 22-64 hours and 118-220 hours as measured in sheep (i.v., i.m.) and cows (i.v., i.m.) respectively.

eCG is mainly degraded in liver and kidney and eliminated in the urine.