Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection
Lyophilisate: freeze-dried product in the form of powder agglomerated in cotton-like pellets.
Solvent: clear colourless solution.
Reconstituted solution: clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

See section 4.7.

4.4 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).

4.5 Special precautions for use

Special precautions for use in animals
In case of anaphylactic shock, symptomatic treatment (e.g. adrenaline or corticosteroids) should be administered.

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

4.6 Adverse reactions (frequency and seriousness)

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 4.5).
The frequency of adverse reactions is defined using the following convention:

- 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).

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

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

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

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

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

4.11 Withdrawal Period(s)

Meat and offal: zero days
Milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: gonadotropins, serum gonadotrophin
ATCvet code: QG03GA03

5.1 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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate: Mannitol.
Solvent:
Benzyl alcohol (E 1519).
Sodium chloride.
Water for injections.

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
Solvent: shelf-life after first opening the vial: 28 days.
Shelf life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

Lyophilisate: protect from light.

Store in a refrigerator (2°C - 8°C)

6.5 Nature and composition of immediate packaging

Primary packaging:
Lyophilisate:
Colourless glass vial type I closed with a chlorobutyl stopper and aluminium capsule.
Solvent:
Colourless glass vial type II closed with a chlorobutyl stopper and aluminium capsule.

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
10, avenue de La Ballastiere
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10815/015/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th January 2011
Date of last renewal: 18th December 2015

10 DATE OF REVISION OF THE TEXT