



# SYNCROPART<sup>®</sup> PMSG

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Product information

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## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncropart PMSG 6000 IU - cattle, sheep, goat.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

### Active substance:

Equine serum gonadotropin (eCG, formerly called PMSG)..... 6000 UI

Excipient q.s. 1 vial

For the full list of excipients, see section 6.1. "List of excipients".

## 3. PHARMACEUTICAL FORM

Lyophilisate for solution for injection.

## 4. CLINICAL PARTICULARS

### 4.1 | Target species

Cattle, sheep and goats.

### 4.2 | Indications for use, specifying the target species

In cows, ewes, ewe-lambs and goats:

- Induction and synchronisation of heat and ovulation.

To be used in combination with a progestagen.

### 4.3 | Contraindications

See section "Use during pregnancy, lactation or laying".

### 4.4 | Special warnings for each target species

In cattle, sheep and goats, the doses of serum equine gonadotropin (eCG) to be administered should be breed-appropriate; especially for sheep, doses should be lower in prolific breeds than in non-prolific breeds, at the season and cyclicity of females (doses should be higher in non-cycling females than in cycling females).

## 4.5 | Special precautions for use

### i : Special precautions for use in animals

Use the reconstituted solution immediately. In case of anaphylactic shock, treatment with adrenaline and glucocorticoids should be initiated promptly.

### ii : Special precautions to be taken by the person administering the veterinary medicinal product to animals

The product must be handled with care to avoid accidental injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label. Wash hands after using the product. Studies in experimental animals have shown teratogenic effects of eCG (formerly PMSG). Women who intend to become pregnant or whose condition is not known should not handle the product. In case of accidental sprinkling, the skin should be washed immediately and thoroughly with soap and water. People with known hypersensitivity to gonadotropins should avoid contact with the product.

### iii : Other precautions

None.

## 4.6 | Adverse reactions (frequency and seriousness)

eCG (formerly PMSG) is a foreign protein for species other than equines. Thus an antigen-antibody reaction can be induced. In very rare cases, repeated administration of eCG may cause anaphylactic shock.

## 4.7 | Use during pregnancy, lactation or lay

Studies in experimental animals have shown teratogenic effects following administration of eCG.

The safety of the veterinary medicinal product has not been established in case of pregnancy.

Do not use during gestation.

## 4.8 | Interaction with other medicinal products and other forms of interaction

Not known.

## 4.9 | Amounts to be administered and administration route

After reconstitution of the lyophilisate, inject intramuscularly, per animal, 2 ml of reconstituted solution on the following bases:

eCG dose selected in IU	300	400	428	461	500	545	600	700
Volume of solvent	40	30	28	26	24	22	20	16
Number of females that can be treated	20	15	14	13	12	11	10	8

#### **Cows and heifers:**

300 to 600 IU intramuscularly, at the end of progestagen therapy; non-cycling animals should receive the highest doses.

#### **Ewe:**

400 - 700 IU IM at the end of progestagen therapy.

The doses administered should be adapted to the breed (lower doses in prolific breeds than in non-prolific breeds) and to the season (higher doses in non-cycling ewes than in cycling ewes).

#### **Goats:**

400 - 600 IU intramuscularly, at the end of progestagen treatment (long protocol: 18 to 21 days of insertion) or 48 h +/-1 h before the end of progestagen treatment (short protocol: 11 days).

Doses administered should be appropriate to the season (higher doses in non-cycling goats than in cycling goats) and milk production.

### **4.10 | Overdose (symptoms, emergency procedures, antidotes), if necessary**

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

### **4.11 | Pharmacodynamic properties**

Meat and offal: zero days

Milk: zero days

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic Group: Gonadotropin and other ovulation stimulants.

ATCvet code: QG03GA03

### **5.1 | Pharmacodynamic properties**

eCG promotes the maturation of ovarian follicles. Its use is recommended after a treatment for the synchronisation of heat with a progestagen: it allows synchronous maturation of the follicles and improves the ovulation rate.

### **5.2 | Pharmacokinetic particulars**

The kinetics of eCG decline biphasically with a terminal half-life of 22-64 hours in sheep (intravenous, intramuscular) and 118-220 hours in cattle (intravenous, intramuscular).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 | List of excipients

Mannitol

### 6.2 | Major incompatibilities

None.

### 6.3 | Shelf life

3 years. After reconstitution: use immediately.

### 6.4 | Special precautions for storage

Store between +2°C and +8°C, protect from light.

### 6.5 | Nature and composition of immediate packaging

#### **Material of the primary packaging:**

Glass vial type I

Chlorobutyl rubber stopper

#### **Pack sizes:**

Cardboard box containing 1 vial of 3 ml of lyophilisate and 1 empty vial of 50 ml

Cardboard box containing 1 vial of 10 ml of lyophilisate

Cardboard box containing 10 vials of 10 ml of lyophilisate

Cardboard box containing of 20 vials of 10 ml of lyophilisate

Cardboard box containing of 24 vials of 10 ml of lyophilisate

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 product should be disposed of in accordance with local requirements.