

Package Insert for a Veterinary Preparation

This drug is only marketed subject to a veterinarian's prescription

For use only in animals

1. Name of the Veterinary Medicinal Product, Its Shape, and Strength :

SYNCROPART PMSG 600 IU VETERINARY

Powder for Preparing a Solution for Intramuscular Injection (IM)

2. Active Substance :

Serum Gonadotrophin 600 IU / Vial

3. What the Medicinal Product Is Intended for :

Encouraging the regulation of estrus and ovulation in ewes, ewe lambs, and nanny goats after the removal of the Syncropart vaginal sponge (which contains progesterone acetate).

Therapeutic group: Gonadotropins

4. Contraindications :

Do not use during pregnancy.

5. Side effects:

The active substance is a protein foreign to the treated animal, which can potentially cause an antigen-antibody interaction or an allergic reaction, in case of anaphylactic shock (rare) .

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects and Drug-related Adverse Events" on the homepage of the Ministry of Health website (www.health.gov.il), which redirects to an online form for reporting side effects, or by clicking on the link <https://sideeffects.health.gov.il/>

6. Target Species:

Ewes, ewe lambs, nanny goats

7. Administration Route, Instructions for Use, and Dose:

The contents of the vial (a dose containing 600 IU) should be dissolved with 2 ml of water for injection and the solution should be injected into the muscle .

8. How to Use the Preparation :

The solution should be used immediately after preparation and injected into the muscle.

9. Withdrawal period:

0 days (meat and milk)

10. Warnings:

Special Warnings Regarding the Use of the Medicinal Product for the Treatment of the Target Species:

Immediately use the dissolved solution.

In case of anaphylactic shock, symptomatic treatment should be given (e.g., administration of steroids or adrenaline).

Special Warnings Regarding the Safety of the Person Administering the Preparation:

Use with caution to prevent accidental injection. In case of self-injection, seek medical treatment and show the leaflet of the medical preparation.

Trials have shown teratogenic reactions after the administration of the preparation.

Pregnant women, women planning to conceive, or women who may be pregnant should avoid providing treatment with this preparation.

Avoid direct contact between the preparation and the skin. In case of skin contact, wash the affected area with soap and water.

People who are known to be sensitive to the active substance or to any of the excipients (listed in Section 13) should abstain from using this medicinal product.

Use in Pregnant or Lactating Animals

The safety of using this preparation during pregnancy has not been established; do not use during pregnancy.

Drug Interactions and Other Forms of Interaction

Unknown

Overdose :

Giving higher doses than those recommended can lead to the birth of twins and triplets in sheep and goats.

11. Storage Instructions:

- Prevent poisoning! This medicinal product and any other medicinal product should be kept in a closed place out of the reach and sight of children and/or babies to prevent poisoning.

- Do not use this medicinal product after the expiry date (Exp. Date), which appears on the package. The expiry date refers to the last day of that month.

Storage conditions : Store refrigerated at a temperature between 2-8°C. Protect from light.

The preparation should be used immediately once the powder has been dissolved (see preparation instructions).

Store out of the reach and sight of children.

12. Instructions Pertaining to the Disposal of the Preparation/Remaining Quantity of the Preparation Once Its Use Is Over:

Do not throw any leftover medicinal products into the gutter or trash can. Ask your veterinarian how to destroy leftover medicinal products to protect the environment.

13. Additional Information

- In addition to the active substance - the medicinal product also contains Mannitol.

- What the Medicinal Product Looks Like and What the Package Content Is :

Package - a box containing 1 vial with powder, or a box containing 25 vials with powder.

Drug Registration Number 080-30-91971 :

Manufacturer : Ceva Sante Animale S.A, Libourne, France

Registration holder : MIP VETERINARIA Ltd., P.O. Box 10437, Haifa, 2611302

Edited in January 2023 pursuant to the directions of the Ministry of Health