CONSUMER PACKAGE INSERT FOR A VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only
For animal use only

1. NAME OF THE VETERINARY MEDICINE, ITS FORM AND STRENGTH:

Chronogest PMSG 6000 I.U. Veterinary
Powder for preparation of a solution for intramuscular injection

2. ACTIVE INGREDIENTS:

Each vial contains:
Pregnant mare serum gonadotrophin 6000 I.U.

A list of inactive ingredients is detailed in section 13 – "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR:

Induction and synchronization of ovulation in sheep, ewes and goats.

Therapeutic group: Sex hormones and modulators of the reproductive system.

Mechanism of action:
When the progestogen sponge is in the vagina of the sheep or goat, it induces progestative activity in the animal, similar to the luteal phase in the reproductive cycle. This artificial progestative period ends as soon as the sponge is removed. At this stage (or, in goats, sometimes two days earlier), injection of Chronogest PMSG induces the commencement of the follicular stage. The follicles that develop lead to the start of the estrus and ovulation at the scheduled time. Chronogest PMSG 6000 I.U. is part of the treatment regimen of Chronogest to control reproduction in sheep and goats.

4. CONTRAINDICATIONS:

Do not use in cases of hypersensitivity to the active ingredient or to any of the inactive ingredients.

5. SIDE EFFECTS:

As with any preparation that contain proteins, anaphylactoid reactions may occur in rare cases (1-10 out of 10,000 treated animals). Treatment based on adrenaline and glucocorticoids must be rapidly administered.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

6. TARGET ANIMALS:

Sheep and goats.

7. METHOD OF ADMINISTRATION AND DOSAGE:

Intramuscular administration.
The dosage of Chronogest PMSG depends on the age of the animal, the breed, the season, etc.

8. HOW TO USE THE MEDICINAL PRODUCT:

Dissolve the medicine in the solvent and inject the required dose by intramuscular injection. Inject the medicine immediately after dissolving it, and dispose of the empty vial after use.

Note:
Chronogest can be used to control reproduction in cattle, in combination with an appropriate progestogenic treatment.

9. WITHDRAWL PERIOD:

Milk: 0 days.
Meat and offal: 0 days.

10. WARNINGS:

- Special warnings for each of the target animals
  Administration of doses higher than those recommended for the medicinal product may increase the risk of triplets in sheep.
  Repeating PMSG treatments may cause the appearance of PMSG antibodies in some goats which may affect the effectiveness of the treatment.
- Special warnings relating to the use of the medicine in animals
  None
- Special warnings relating to the safety of the person administering the medicinal product
  In the event of accidental contact with the skin, immediately wash the contaminated area with soap and water.
  In the event of accidental self-injection, consult the doctor immediately and show him the leaflet or the label of the product.
- Pregnancy and lactation of the treated animal
  Do not use on pregnant females.
- Interactions with other medicinal products, and other forms of interaction
  Unknown.
- Overdose
  See section “Special warnings for each of the target animals”.
- Incompatibilities
  Do not mix with other products, other than the solvent provided for this purpose.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions:
  Store the dry powder in a refrigerator between 2°C-8°C.
  Shelf life after reconstitution: Use immediately.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER USE:

All remnants of a veterinary medicinal product, or any waste obtained upon use of a veterinary medicinal product must be discarded as toxic waste, do not throw to sewer.

13. FURTHER INFORMATION:

- In addition to the active ingredient(s), the medicine also contains:
  Mannitol, Sodium Dihydrogen Phosphate, Disodium Hydrogen Phosphate.
- What the medicine looks like and the contents of the package:
  A glass vial with a rubber stopper. Each vial contains 6000 International Units of serum gonadotrophin, in the form of a white to almost white, sterile, lyophilized powder.
  Package size: A package containing one or 10 vials of powder.
  Not all package sizes may be marketed.
- Registration holder:
  Intervet Israel Ltd., Neve Ne'eman Industrial Park, Hod Hasharon 45240.
- Manufacturer and address:
  Intervet International B.V., Wim de Koerverstraat 35, 5830 AA Boxmeer, Netherlands
- Revised in August 2022 according to MOH guidelines.
- Registration number of the medicinal product in the National Drug Registry of the Ministry of Health: 083-72-92133