B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

OVISER 5000 IU lyophilisate and solvent for solution for injection.

2. Composition

Each vial of lyophilisate contains:
Active substance
Pregnant Mare Serum Gonadotrophin (PMSG) 5000 IU

Each vial of solvent contains:
Phosphate buffer solution (PBS) 50 ml

Each vial of lyophilisate is dissolved in the proper volume of solvent for reconstitution (50 ml). The final concentration of PMSG is 100 IU/ml.

Lyophilisate: white lyophilisate tablet, fragile, approximately 0.5 cm thick.
Solvent: transparent, colourless liquid.
Reconstituted solution: transparent, colourless liquid.

3. Target species

Sheep (ewe) and goat.

4. Indications for use

Sheep (ewe) and goat: Induction of heat and ovulation. Synchronisation of heat.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer to females with polycystic ovaries.
See special warning during pregnancy and lactation.

6. Special warnings

Special precautions for safe use in the target species:
Adjust the dosage. A higher dose of PMSG does not entail an increase in the efficacy of the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Administer the veterinary medicinal product with precaution.
In the event of contact with eyes or skin, wash with abundant water for several minutes.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

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

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No adverse reactions occurred when a dose of 3000 IU/animal (5 times the recommended dose) was administered.
Higher doses of PMSG do not increase the efficacy of the product.
An overdose of PMSG may give rise to superovulations and/or gestations with an elevated number of young. This implies an increase in the embryonic and neonatal mortality rate. It may also, over time, cause the synthesis of anti-PMSG antibodies.
An excessive concentration of PMSG would prolong the presence of antrum and/or pre-ovulatory follicles that could lead to ovarian cysts.

Special restrictions for use and special conditions for use:
Administration by a veterinary surgeon or under their direct responsibility.

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

7. Adverse events

Sheep (ewe) and goat:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Rash, anaphylactic shock.*

* Observed in sensitive animals. In such case, an adrenalin injection or corticoids by intravenous or intramuscular route when the first symptoms appear shall be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Administration route: intramuscular or subcutaneous.
Administer 400-600 IU/animal: equivalent to 4-6 ml of the reconstituted product per animal.
It is recommended to administer one single dose after the treatment with progestagens.

9. Advise on correct administration

The lyophilisate should be reconstituted using the entire volume of solvent (50 ml of PBS).
Dissolve the lyophilisate in a small quantity of solvent. Mix until a homogenous solution is obtained. Introduce this solution into a vial containing the rest of the solvent and mix until completely dissolved.
The final concentration of PMSG is 100 IU/ml.

10. Withdrawal periods

Meat and offal: zero days.
Milk: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Keep the lyophilisate vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Unitary pack size: 1 cardboard box containing 1 vial of lyophilisate and 1 cardboard box containing 1 vial of solvent.
Clinical pack size: 1 cardboard box containing 10 vials of lyophilisate and 1 cardboard box containing 10 vials of solvent.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona) SPAIN
Tel. +34 972 43 06 60 - Fax. +34 972 43 06 61
E-mail: hipra@hipra.com

<Local representatives and contact details to report suspected adverse reactions:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

<{Local representative contact details}>