[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVISER 5000 IU lyophilisate and solvent for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

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

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Povidone
Mannitol
Simethicone emulsion 30%
Solvent:
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Sodium chloride
Potassium chloride
Water for injectable preparations

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. CLINICAL INFORMATION

3.1 Target species

Sheep (ewe) and goat.

3.2 Indications for use for each target species

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

3.3 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 section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Administration by a veterinary surgeon or under their direct responsibility.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03GA03.

4.2 Pharmacodynamics

PMSG has a physiological activity similar to follicle stimulating hormone (FSH), although it also shows certain activity typical of luteinising hormone (LH) due to its ability to bind with FSH/LH receptors. The interaction between PMSG and FSH receptors induces the production of oestrogens that are responsible to stimulate the sexual behaviour, even during the non-reproductive season; also, the association with LH receptors stimulates ovulation in the females treated.

This elevated production of oestrogens activates a cascade of hormonal reactions that stimulates an increase in the number and proliferation of follicles. It likewise stimulates the growth and maturation of the ovarian follicles and the formation of corpora lutea, leading to the consequent ovulation between 36 and 72 hours post-treatment.

PMSG can be used in conjunction with progestagens in oestrus synchronisation protocols.

4.3 Pharmacokinetics

When PMSG is administered by oral route, it is destroyed by gastrointestinal tract enzymes. Therefore, it is only effective after being administered by parenteral route. Absorption by intramuscular and subcutaneous route is very similar.

After intramuscular or subcutaneous administration, the absorption of PMSG reaches maximum serum concentrations between 12 and 24 hours post-administration.

This hormone follows a bicompartimental model with rapid distribution and a slow elimination phase. It is also filtered across the placenta from the maternal system so it is contraindicated in gestating females.

PMSG metabolises at a hepatic level and a very little quantity is excreted in the urine (1%). Due to its richness in sialic acid and its large molecular weight it has a long half-life, between 24-26 hours, and its elimination half-life that is between 40 and 125 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Keep the lyophilisate vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

The lyophilisate is filled in 10 ml colourless Type I glass vials, closed with Type I bromobutyl rubber closures with anodised aluminium caps.

The solvent is filled in 50 ml colourless Type II glass vials (containing 50 ml of solvent), closed with Type I bromobutyl rubber closures with anodised aluminium caps.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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