SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET 400/200 IU lyophilisate and solvent for solution for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Liophilisate vial contains:
Active substances:
Equine Serum Gonadotrophin (PMSG) ……. 400 IU
Chorionic Gonadotrophin (HCG) …….. 200 IU

Excipients, q.s.

Solvent vial (5 ml) contains:
Excipients, q.s.

One ml of reconstituted solution contains:
Active substances:
Equine Serum Gonadotrophin (PMSG) ……. 80 IU
Chorionic Gonadotrophin (HCG) …….. 40 IU

Excipients, q.s.

Each reconstituted 5 ml dose contains:
Active substances:
Equine Serum Gonadotrophin (PMSG) ……. 400 IU
Chorionic Gonadotrophin (HCG) …….. 200 IU

Excipients, q.s.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.
White, fragile, lyophilisate with clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows).

4.2 Indications for use, specifying the target species

Sows: Induction and synchronization of heat.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.
Do not use in sows with polycystic ovaries.
Do not use in pregnant animals.

4.4 Special warnings for each target species

Treatment during the primary luteinized phase or in the middle of the cycle may increase the development of ovarian cysts.

The administration of this veterinary medicinal product induces heat between 3 and 6 days after treatment.

Do not adjust the dose. High doses do not increase the efficacy of the veterinary medicinal product.

4.5 Special precautions for use

Special precautions for use in animals

Do not inject into the subcutaneous fat.
Shake the vial well to obtain a homogenous solution.

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

Care should be taken to avoid accidental self-injection; if accidental self-injection occurs, seek medical advice and show this package or label to your physician.
The veterinary medicinal product can provoke a slight skin irritation. Avoid contact with skin and wear protective gloves. Accidental spillage should be rinsed immediately with plenty of water.
Do not handle the veterinary medicinal product if you are hypersensitive to gonadotropins.
Studies with laboratory animals exhibited teratogenic effects after the administration of the combination HCG/PMSG. Pregnant women, women intending to become pregnant, or women whose pregnancy status is unknown should not use the veterinary medicinal product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In the unlikely event of an individual anaphylactic reaction, 1-3 ml Adrenaline 1:1000 solution should be given by intramuscular injection.

The PMSG and the HCG are exogenous proteins for other species than equine and human. Therefore, an antigen-antibody reaction can be inferred. The repeated administration of PMSG and HCG can provoke in rare cases an anaphylactic shock.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Intramuscular use, behind the base of the ear.
Dissolve the lyophilisate part with a small quantity of solvent. Mix to obtain a homogenous solution. Transfer this solution into the vial that contains the rest of the solvent and mix until completely dissolved.

Administer immediately after product reconstitution.

Pigs: 5 ml/sow (i.e. 400 IU PMSG and 200 IU HCG per animal), in a single administration from 0 to 2 days after the weaning.

The heat will be induced between 3 and 6 days after veterinary medicinal product administration.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose will not provoke adverse reactions, but better results are not obtained by administering a dose higher than that recommended.

4.11 Withdrawal period(s)

Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropins, combinations.
ATCvet codes: QG03GA99 Gonadotropins, combinations
QG03GA01 Chorionic gonadotrophin
QG03GA03 Serum gonadotrophin

5.1 Pharmacodynamic properties

The veterinary medicinal product is a lyophilisate presentation of HCG and PMSG in combination with solvent for reconstitution. The veterinary medicinal product contains 400 IU of PMSG and 200 IU of HCG.

PMSG displays dual FSH and LH activities. It therefore stimulates follicular growth and follicular maturation during the days preceding oestrus and ovulation. HCG displays only LH like activity. It therefore plays a key role in the induction of ovulation of the follicles stimulated to grow by PMSG. This explains why the veterinary medicinal product efficiently induces and synchronizes the first post weaning ovulation in sows.

5.2 Pharmacokinetic particulars

After injection to pigs, PMSG and HCG are rapidly absorbed as, for both hormones, Cmax is reached within 8 hours for both hormones. Bioavailability following i.m. injection is high. In pigs the elimination half lives of PMSG and HCG were shown to be 36 and 27 hours respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate vial:
Potassium dihydrogen phosphate.
Disodium phosphate dodecahydrate.
Lactose monohydrate.
Solvent vial:
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Keep the vial in the outer carton.

6.5 Nature and composition of immediate packaging

Carton box containing 5 vials of lyophilisate and 5 vials of solvent (5ml/vial).
Carton box containing 10 vials of lyophilisate and carton box containing 10 vials of solvent (5ml/vial).

The lyophilisate product 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 10 ml colourless Type I glass vials (containing 5 ml of solvent), closed with Type I bromobutyl rubber closures with anodised aluminium caps.

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.

7. MARKETING AUTHORISATION HOLDER

Biogénesis Global, S.L.
Manuel Pombo Angulo, 28
28050 Madrid
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 57571/4000

9. DATE OF FIRST AUTHORISATION

01 July 2009

10. DATE OF REVISION OF THE TEXT

February 2023

Approved 06 February 2023