

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml (40IU/ml 80IU/ml) lyophilisate and solvent for solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Chorionic Gonadotrophin (HCG).....1000 IU
Equine Serum Gonadotrophin (PMSG).....2000 IU

Excipients

Qualitative composition of excipients and other constituents
Potassium dihydrogen phosphate.
Disodium phosphate dodecahydrate.
Lactose monohydrate.
Sodium hydroxide (pH adjuster)
Hydrochloric acid (pH adjuster)
Solvent vial:
Water for injections

Each vial of lyophilisate is reconstituted with 25 ml of solvent. The reconstituted solution contains 40 IU of HCG and 80 IU. of PMSG per ml

Lyophilisate: a white and fragile freeze-dried tablet.

Solvent: a clear and colourless liquid.

Reconstituted solution: a clear and colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows).

3.2 Indications for use for each target species

Induction and synchronization of heat.

3.3 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for use in the target species:

Do not inject into the subcutaneous fat.

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

Care should be taken to avoid accidental self-injection; in case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

People with known hypersensitivity to gonadotropins should avoid contact with the veterinary medicinal products.

The veterinary medicinal product can provoke a slight skin irritation. Avoid contact with skin. Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product. Accidental spillage should be rinsed immediately with plenty of water.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows):

Uncommon (1 to 10 animals / 1 000 animals treated):	Anaphylactic shock ¹
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¹In the unlikely event of an individual anaphylactic reaction, 1-3 ml Adrenaline 1:1000 solution should be given by intramuscular injection.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use in pregnant animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

Shake the vial well to obtain a homogenous solution.

Administer immediately after product reconstitution.

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.

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

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

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

For administration only by a veterinarian.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet codes: QG03GA99 Gonadotropins, combinations

4.2 Pharmacodynamics

The veterinary medicinal product is a lyophilisate presentation of HCG and PMSG in combination with solvent for reconstitution. The veterinary medicinal product contains 2000 IU of PMSG and 1000 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.

4.2 Pharmacokinetics

After injection to pigs, PMSG and HCG are rapidly absorbed as, for both hormones, C_{max} 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.

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). Protect from light.

Keep the vial in the outer carton.

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 25 ml of solvent), closed with Type I bromobutyl rubber closures with anodised aluminium caps.

Pack size:

Carton box containing 10 vials of lyophilisate

Carton box containing 10 vials of solvent (25ml/vial).

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Biogénesis Global, S.L.

7. MARKETING AUTHORISATION NUMBER

Vm 57571/4001

8. DATE OF FIRST AUTHORISATION

16 December 2009

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

August 2026

10. CLASSIFICATION OF THE VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.