

[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET 3000 lyophilisate and solvent for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)

GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml lyophilisate and solvent for solution for injection for pigs. (AT)

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

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

SUIGEST 3000 lyophilisate and solvent for solution for injection for pigs. (EL)

GESTAVET HCG 1000 / PMSG 2000 lyophilisate and solvent for solution for injection for pigs. (ES)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyophilisate vial contains:

Active substances

Equine Serum Gonadotrophin (PMSG) 2000 IU

Chorionic Gonadotrophin (HCG)..... 1000 IU

Excipients, q.s

Solvent vial (25 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-HCG

QG03GA03 Serum gonadotrophin-PMSG

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 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.

5.2 Pharmacokinetic particulars

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.

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 10 vials of lyophilisate

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

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.

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

LABORATORIOS HIPRA, S.A.

Avda. la Selva, 135

17170-AMER (Girona) España

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/05/2009.

Date of last renewal: {DD/MM/YYYY}.

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only. To be supplied only on veterinary prescription.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**10 vials of lyophilisate****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

GESTAVET 3000 lyophilisate for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)
GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml lyophilisate for solution for injection for pigs. (AT)
GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate for solution for injection for pigs. (UK)
GESTAVET HCG 40 IE/ml / PMSG 80 IE/ml lyophilisate for solution for injection for pigs. (DE)
SUIGEST 3000 lyophilisate for solution for injection for pigs. (EL)
GESTAVET HCG 1000 / PMSG 2000 lyophilisate for solution for injection for pigs. (ES)

Chorionic and Equine Serum Gonadotropins.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**Each lyophilisate vial of 5 doses contains:**

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

3. PHARMACEUTICAL FORM

Lyophilisate for solution for injection.

4. PACKAGE SIZE

10 vials of lyophilisate

5. TARGET SPECIES

Pigs (sows).

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY
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Care should be taken to avoid accidental self-injection. Pregnant women, women intending to become pregnant, or women whose pregnancy status is unknown should not use the veterinary medicinal product. Read the package leaflet for full user warnings.

10. EXPIRY DATE

EXP

Once reconstituted, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).

Protect from light.

Keep the vial in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
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Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

Avda. la Selva, 135

17170 AMER (Girona)

Spain

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER'S BATCH NUMBER
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Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**10 vials of solvent (25 ml)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Solvent for use with **GESTAVET 3000** lyophilisate for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)

Solvent for use with **GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml** lyophilisate for solution for injection for pigs. (AT)

Solvent for use with **GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml** lyophilisate for solution for injection for pigs. (UK)

Solvent for use with **GESTAVET HCG 40 IE/ml / PMSG 80 IE/ml** lyophilisate for solution for injection for pigs. (DE)

Solvent for use with **SUIGEST 3000** lyophilisate for solution for injection for pigs. (EL)

Solvent for use with **GESTAVET HCG 1000 / PMSG 2000** lyophilisate for solution for injection for pigs. (ES)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Water for injections25 ml

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

4. PACKAGE SIZE

10 x 25 ml

5. TARGET SPECIES

Pigs (sows).

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY
--

Care should be taken to avoid accidental self-injection. Pregnant women, women intending to become pregnant, or women whose pregnancy status is unknown should not use the veterinary medicinal product. Read the package leaflet for full user warnings.

10. EXPIRY DATE

EXP

Once reconstituted, use immediately.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
--

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)
--

17. MANUFACTURER'S BATCH NUMBER
--

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**Vial of lyophilisate****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

GESTAVET 3000 lyophilisate for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)
GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml lyophilisate for solution for injection for pigs. (AT)
GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate for solution for injection for pigs. (UK)
GESTAVET HCG 40 IE/ml / PMSG 80 IE/ml lyophilisate for solution for injection for pigs. (DE)
SUIGEST 3000 lyophilisate for solution for injection for pigs. (EL)
GESTAVET HCG 1000 / PMSG 2000 lyophilisate for solution for injection for pigs. (ES)

Chorionic and Equine Serum Gonadotropins.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each lyophilisate vial of 5 doses contains:

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read package leaflet before use.

5. WITHDRAWAL PERIOD

Meat and offal: zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:
Once reconstituted, use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**Vial of solvent****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Solvent for use with **GESTAVET 3000** lyophilisate for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)

Solvent for use with **GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml** lyophilisate for solution for injection for pigs. (AT)

Solvent for use with **GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml** lyophilisate for solution for injection for pigs. (UK)

Solvent for use with **GESTAVET HCG 40 IE/ml / PMSG 80 IE/ml** lyophilisate for solution for injection for pigs. (DE)

Solvent for use with **SUIGEST 3000** lyophilisate for solution for injection for pigs. (EL)

Solvent for use with **GESTAVET HCG 1000 / PMSG 2000** lyophilisate for solution for injection for pigs. (ES)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Water for injections25 ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Meat and offal: zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

Once reconstituted, use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

GESTAVET 3000 lyophilisate and solvent for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)

GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml lyophilisate and solvent for solution for injection for pigs. (AT)

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

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

SUIGEST 3000 lyophilisate and solvent for solution for injection for pigs. (EL)

GESTAVET HCG 1000 / PMSG 2000 lyophilisate and solvent for solution for injection for pigs. (ES)

Chorionic and Equine Serum Gonadotropins.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

LABORATORIOS HIPRA, S.A.

Avda. la Selva, 135

17170-AMER (Girona) España

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET 3000 lyophilisate and solvent for solution for injection for pigs. (BE, FR, IT, LT, MT, NL & PT)

GESTAVET HCG 1000 IE/ml / PMSG 2000 IE/ml lyophilisate and solvent for solution for injection for pigs. (AT)

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

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

SUIGEST 3000 lyophilisate and solvent for solution for injection for pigs. (EL)

GESTAVET HCG 1000 / PMSG 2000 lyophilisate and solvent for solution for injection for pigs. (ES)

Chorionic and Equine Serum Gonadotropins.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

White, fragile, lyophilisate with clear, colourless solution.

Each lyophilisate vial of 5 doses contains:

Equine Serum Gonadotrophin (PMSG) 2000 IU

Chorionic Gonadotrophin (HCG)..... 1000 IU

One ml of reconstituted solution contains:

Active substances

Equine Serum Gonadotrophin (PMSG) 80 IU

Chorionic Gonadotrophin (HCG)..... 40 IU

After reconstitution with 25 ml solvent, each 5 ml dose contains:

Equine Serum Gonadotrophin (PMSG) 400 IU

Chorionic Gonadotrophin (HCG)..... 200 IU

4. INDICATION(S)

Sows: Induction and synchronization of heat.

5. 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.

6. ADVERSE REACTIONS

In the unlikely event of an anaphylactic reaction, apply the appropriate treatment.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sows)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular, 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 weaning.

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

9. ADVICE ON CORRECT ADMINISTRATION

After reconstitution it is a clear and colourless liquid.

10. WITHDRAWAL PERIOD

Meat and offal: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Protect from light.

Keep the vial in the outer carton.

Once reconstituted, use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The 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.

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. Avoid contact with skin and wear protective gloves. Accidental spillage should be rinsed immediately with plenty of water. Wash hand after use.

Do not handle the veterinary medicinal product if you are hypersensitive to gonadotropins.

Pregnant women, women intending to become pregnant, or women whose pregnancy status is unknown should not use the veterinary medicinal product.

Use during pregnancy, lactation or lay:

Do not use in pregnant animals.

Overdose (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Presentations:

Box with 10 vials of lyophilisate and box with 10 vials of solvent.

For animal treatment only.

To be supplied only on veterinary prescription.