

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 vials of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate for solution for injection for pigs.

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 injectable solution.

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

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”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL, S.L.

Manuel Pombo Angulo, 28

28050 Madrid

Spain

Local Representative:

HIPRA UK AND IRELAND, Ltd.

Innovation Center, Office 503

BioCity Nottingham

Pennyfoot Street

Nottingham

NG1 1GF - UNITED KINGDOM

e-mail: ukandireland@hipra.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57571/4001

17. MANUFACTURER'S BATCH NUMBER

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 HCG 40 IU/ml / PMSG 80 IU/ml** lyophilisate for solution for injection for pigs.

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

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 57571/4001

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 HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate for solution for injection for pigs.

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.

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Water for injections.....25 ml

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.

Local Representative:
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Innovation Center, Office 503
BioCity Nottingham
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**PACKAGE LEAFLET FOR:
GESTAVET HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate and solvent for solution for
injection for pigs.**

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:

BIOGÉNESIS GLOBAL, S.L.
Manuel Pombo Angulo, 28
28050 Madrid
Spain

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 HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate and solvent for solution for
injection for pigs.**

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:

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

February 2023

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.

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Innovation Center, Office 503
BioCity Nottingham
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NG1 1GF - UNITED KINGDOM
e-mail: ukandireland@hipra.com

Approved 06 February 2023

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and cursive.