

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**5 vials of lyophilisate + 5 vials of solvent**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

Equine Serum and Chorionic Gonadotropins.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

**Each reconstituted 5 ml dose contains:**

Equine Serum Gonadotrophin (PMSG) .....400 IU

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

**3. PHARMACEUTICAL FORM**

Lyophilisate and solvent for solution for injection.

**4. PACKAGE SIZE**

5 vials of lyophilisate + 5 vials of solvent

**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 57571/4000

**17. MANUFACTURER'S BATCH NUMBER**

Batch:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**10 vials of lyophilisate**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**GESTAVET 400/200 IU** lyophilisate for solution for injection for pigs.

Equine Serum and Chorionic Gonadotropins.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

**Each lyophilisate vial of 1 dose contains:**

Equine Serum Gonadotrophin (PMSG) .....400 IU

Chorionic Gonadotrophin (HCG) .....200 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**

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 57571/4000

**17. MANUFACTURER'S BATCH NUMBER**

Batch:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**10 vials of solvent (5 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Solvent for use with **GESTAVET 400/200 IU** lyophilisate for solution for injection for pigs.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Water for injections .....5 ml

**3. PHARMACEUTICAL FORM**

Solvent for parenteral use.

**4. PACKAGE SIZE**

10 x 5 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**

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 57571/4000

**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 400/200 IU** lyophilisate for solution for injection for pigs.

Equine Serum and Chorionic Gonadotropins.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**Each lyophilisate vial (1 dose) contains:**

Equine Serum Gonadotrophin (PMSG).....400 IU  
Chorionic Gonadotrophin (HCG) .....200 IU

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

1 dose

**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:  
HIPRA UK AND IRELAND, Ltd.  
Innovation Center, Office 503  
BioCity Nottingham  
Pennyfoot Street

Nottingham  
NG1 1GF - UNITED KINGDOM  
e-mail: ukandireland@hipra.com

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial of solvent**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Solvent for use with **GESTAVET 400/200 IU** lyophilisate for solution for injection for pigs.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Water for injections.....5 ml

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

1 dose

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



**PACKAGE LEAFLET FOR:**  
**GESTAVET 400/200 IU** lyophilisate and solvent for solution for injection for pigs.

Equine Serum and Chorionic 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 400/200 IU** lyophilisate and solvent for solution for injection for pigs.

Equine Serum and Chorionic Gonadotropins.

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

White, fragile, freeze-dried powder with clear, colourless solution.

Each reconstituted 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 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 5 vials of lyophilisate and 5 vials of solvent.

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

Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY  
TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

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

Approved 06 February 2023

A handwritten signature in black ink, consisting of a stylized, looped initial followed by the name "Hunter." in a cursive script.