

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing one vial of lyophilisate and one 25 ml vial solvent
Box containing ten vials of lyophilisate and ten 25 ml vial solvent.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fertipig HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate and solvent for solution for injection for pigs [AT, DE, DK, IE, UK]
Fertipig lyophilisate and solvent for solution for injection for pigs [BE, BG, CY, EL, ES, FR, HU, IT, LU, NL, PL, PT, RO, SK]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of reconstituted solution contains:
Equine serum gonadotrophin (PMSG) 80 IU, Gonadotrophin chorionic (HCG) 40 IU
Benzyl alcohol 15 mg

One 5 ml dose contains 400 IU PMSG, 200 IU HCG and 75 mg benzyl alcohol.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection

4. PACKAGE SIZE

1 vial of lyophilisate (5 doses)
25 ml vial of solvent

10 vials of lyophilisate (10 x 5 doses)
10 25 ml 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 and disposal.

8. WITHDRAWAL PERIOD

Meat and offal: 0 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use and disposal.

10. EXPIRY DATE

EXP:

Once reconstituted, use within 28 days, stored in a refrigerator (2°C - 8°C), by ___/___/___.

11. SPECIAL STORAGE CONDITIONS

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

Read the package leaflet before use and disposal.

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Lyophilisate vial: 5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fertipig HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate for solution for injection for pigs [AT, DE, DK, IE, UK]

Fertipig lyophilisate for solution for injection for pigs [BE, BG, CY, EL, ES, FR, HU, IT, LU, NL, PL, PT, RO, SK]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 vial contains:

Equine serum gonadotrophin (PMSG) 2 000 IU, Gonadotrophin chorionic (HCG) 1 000 IU

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

5 doses

4. ROUTE(S) OF ADMINISTRATION

I.M.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Meat and offal: 0 days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Solvent vial: 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fertipig HCG 40 IU/ml / PMSG 80 IU/ml solvent for solution for injection for pigs [AT, DE, DK, IE, UK]

Fertipig solvent for solution for injection for pigs [BE, BG, CY, EL, ES, FR, HU, IT, LU, NL, PL, PT, RO, SK]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 vial contains: Excipient: Benzyl alcohol 375 mg

1 ml of reconstituted solution contains:

Equine serum gonadotrophin (PMSG) 80 IU, Gonadotrophin chorionic (HCG) 40 IU

Benzyl alcohol 15 mg

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

25 ml (5 doses).

4. ROUTE(S) OF ADMINISTRATION

I.M.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Meat and offal: 0 days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

Once reconstituted, use within 28 days, stored in a refrigerator (2°C - 8°C), by ___/___/___.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Fertipig HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate and solvent for solution for injection for pigs
[AT, DE, DK, IE, UK]

Fertipig lyophilisate and solvent for solution for injection for pigs [BE, BG, CY, EL, ES, FR, HU, IT,
LU, NL, PL, PT, RO, SK]

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

Marketing authorisation holder:

{Name and address}

Manufacturer for the batch release:

Ceva Sante Animale, 10 avenue de La Ballastière, 33500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fertipig HCG 40 IU/ml / PMSG 80 IU/ml lyophilisate and solvent for solution for injection for pigs
[AT, DE, DK, IE, UK]

Fertipig lyophilisate and solvent for solution for injection for pigs [BE, BG, CY, EL, ES, FR, HU, IT,
LU, NL, PL, PT, RO, SK]

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Lyophilisate vial contains:

Active substances

Equine serum gonadotrophin (PMSG)	2 000 IU
Gonadotrophin chorionic (HCG)	1 000 IU

Solvent vial contains:

Excipients

Benzyl alcohol (E1519)	375 mg
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One ml of reconstituted solution contains:

Active substances

Equine serum gonadotrophin (PMSG)	80 IU
Gonadotrophin chorionic (HCG)	40 IU

Excipients

Benzyl alcohol (E1519)	15 mg
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Reconstituted solution for 1 dose of 5 ml contains:

Active substances

Equine serum gonadotrophin (PMSG)	400 IU
Gonadotrophin chorionic (HCG)	200 IU

Excipients

Benzyl alcohol (E1519)	75 mg
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Lyophilisate: white to off-white freeze-dried powder.

Solvent: clear colourless solution.

Reconstituted solution: clear colourless solution.

4. INDICATIONS

To sows after weaning:

Induction and synchronization of oestrus within 7 days following the treatment.

Reduction of the weaning to oestrus interval in sows with late oestrus.

Treatment of the seasonal anoestrus.

5. CONTRAINDICATIONS

Do not administer to pregnant animals.

Do not administer to animals with known hypersensitivity to the active substances or to any of the excipients.

Do not administer to sows with follicular cysts.

6. ADVERSE REACTIONS

In rare cases anaphylactic shock is seen by repeated administration of PMSG and HCG, since PMSG and HCG are exogenous proteins for other species than equine and human and therefore can provoke an antigen-antibody reaction. In case of anaphylactic shock, appropriate treatment should be administered.

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

The frequency of possible adverse reactions is defined using the following convention:

- very common (affects more than 1 animal in 10)
- common (affects 1 to 10 animals in 100)
- uncommon (affects 1 to 10 animals in 1,000)
- rare (affects 1 to 10 animals in 10,000)
- very rare (affects less than 1 animals in 10,000)
- not known (frequency cannot be estimated from the available data).

7. TARGET SPECIES

Pigs (sows).

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

Intramuscular use.

400 IU of equine serum gonadotrophin and 200 IU of chorionic gonadotrophin per animal, i.e. 5 ml of the reconstituted solution in one administration within 24 hours after the weaning.

9. ADVICE ON CORRECT ADMINISTRATION

Dissolve the lyophilisate 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. Shake the vial well to obtain homogenous solution.

10. WITHDRAWAL PERIOD

Meat and offal: 0 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the vial label and carton after EXP.

After reconstitution, store in a refrigerator (2°C - 8°C).
Shelf-life after reconstitution according to directions: 28 days.

12. SPECIAL WARNINGS

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

Do not adjust the dose. Increased doses do not increase the efficacy of the product.

Special precautions for use in animals

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 the package leaflet or the label to the physician.

Wash hands after handling the product. The product can cause a slight skin irritation. When the product comes into contact with the skin, rinse immediately with plenty of water.

Pregnant women, women intending to become pregnant or whose pregnancy status is unknown, should not use the product due to the risk of unintended self injection. Studies in laboratory animals exhibited dose-dependent teratogenic effects after the administration of the combination HCG / PMSG.

People with known hypersensitivity to gonadotrophins should avoid contact with the product.

Use during pregnancy, lactation or lay

Do not administer to pregnant animals. Laboratory studies in laboratory animals have shown evidence of teratogenic effects after combined use of PMSG and HCG.

Overdose

A transient increase in progesterone level was observed following administration of 3 times the recommended dose, following the first oestrus.

An induration and a transient erythema have been observed at the injection site during the product administration with three times the therapeutic dose.

The daily administration of the therapeutic dose during 12 consecutive days can lead to the occurrence of ovarian cysts.

Interactions and 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 material 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

{month/year}

15. OTHER INFORMATION

Pharmacodynamic properties

Equine serum gonadotrophin (PMSG) and human chorionic gonadotrophin (HCG) are high molecular weight glycoproteins. Their structures are similar to the endogenous gonadotrophins, FSH and LH. In females, the PMSG stimulates the growth and development of antral follicles while the HCG participates in follicular maturation and induction of ovulation. Furthermore, HCG facilitates corpus luteum formation resulting in progesterone production.

Package size

Cardboard carton containing one vial of lyophilisate and one 25 ml vial solvent.
Cardboard carton containing ten vials of lyophilisate and ten 25 ml vials solvent.

Once reconstituted the product contains five doses (5 ml/dose).

Not all pack sizes may be marketed.