SUMMARY OF PRODUCT CHARACTERISTICS

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. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

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

For the full list of excipients, see section 6.1..

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.
Lyophilisate: white to off-white freeze-dried powder.
Solvent: clear colourless solution.
Reconstituted solution: clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows).

4.2 Indications for use, specifying the target species

To sows after weaning:

- Induction and synchronization of œstrus within 7 days following the treatment.
- Reduction of the weaning to oestrus interval in sows with late oestrus.
- Treatment of the seasonal anoestrus.

4.3 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.

4.4 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.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not inject into the subcutaneous fat.

ii) Special precautions to be taken by the person administering the medicinal products 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 hypersentivity to gonadotrophins should avoid contact with the product.

4.6 Adverse reactions (frequency and seriousness)

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.
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).

4.7 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.

4.8 Interaction with other medicinal products and the other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Intramuscular use.
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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: gonadotrophin combination.
Code ATC-vet: QG03GA99: gonadotrophin combination
QG03GA01: human chorionic gonadotrophin (HCG)
QG03GA03: equine serum gonadotrophin (PMSG)

5.1 Pharmacodynamic properties

Equine serum gonadotrophin (PMSG) and human chorionic gonadotrophin (HCG) are high molecular weight glycoproteins that are secreted during gestation in mares and women respectively. Their structures are similar to the endogenous gonadotrophins, FSH and LH.
PMSG and HCG bind to FSH and LH receptors of the target cells located in the gonads. 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.

5.2 Pharmacokinetics particulars

After a single intramuscular administration, the pharmacokinetic profile of PMSG and HCG are similar and characterized by:

- fast decrease of the plasma concentrations followed by a period of slower elimination where PMSG and HCG persist in the plasma for a longer time.
- fast distribution mainly to the ovaries, but also to the liver and kidneys.
- biotransformation in the liver, kidneys and ovaries leading to release of alpha and beta sub-units and amino acids.
- urinary elimination mainly as metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate: mannitol.
Solvent:
Benzyl alcohol (E1519).
Sodium dihydrogen phosphate dihydrate.
Disodium phosphate dihydrate.
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: 3 years.
Shelf-life after reconstitution according to directions: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After reconstitution, store in a refrigerator (2°C - 8°C).

6.5 Nature and contents of immediate packaging

Lyophilisate:
10 ml colourless glass vial type I closed with a chlorobutyl stopper and aluminium overseal.

Solvent:
25 ml colourless glass vial type II closed with a chlorobutyl stopper and aluminium overseal.

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.

6.6 Special precautions for the disposal of unused product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

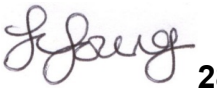
Vm 15052/4050

9. DATE OF THE FIRST AUTHORISATION

Date: 22 January 2010

10. DATE OF REVISION OF THE TEXT

Date: October 2014

Approved:  **28/10/2014**