ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folliplan, 4 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Altrenogest 4.0 mg.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E321)	0.07 mg
Butylhydroxyanisole (E320)	0.07 mg
Soybean oil, refined	

Clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows, nulliparous)

3.2 Indications for use for each target species

For the synchronisation and control of oestrus in cycling nulliparous sows.

3.3 Contraindications

Do not use in male animals.
Do not administer to pregnant sows or those suffering from uterine infection.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Use only in sexually mature sows who had already presented one oestrus.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product should not be administered by women who are, or maybe pregnant. Women of childbearing age should avoid contact with the veterinary medicinal product.

This veterinary medicinal product should not be handled by:
- persons with known or suspected progesterone-dependent tumours
- persons with thrombo-embolic disorders

Avoid contact with the skin and eyes. In case of accidental spillage onto skin it should be washed off immediately with soap and water. In case of accidental contact with the eyes, rinse thoroughly with water for 15 minutes and seek medical advice immediately and show the package leaflet or the label to the physician.

Personal protective equipment consisting of overalls and gloves should be worn when handling the veterinary medicinal product. This veterinary medicinal product can penetrate latex or other types of porous gloves. Absorption through the skin may be even higher when the area is covered by an occlusive material.

Wash hands after use.

Effects of overexposure: repeated accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache.

Special precautions for the protection of the environment:
When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, because the manure may contain altrenogest which could cause adverse effects in the aquatic environment.

3.6 Adverse events

Pigs (sows, nulliparous):

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See also the combined label and package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

In-feed use.
Add the veterinary medicinal product to the feed immediately before feeding.

5 ml (corresponding to 20 mg altrenogest) per animal during 18 days.

Remove the screw cap and the obturator and measure the clinical dose of 5 mL using the dosing cup provided, pour the dose on the feed and close the bottle with the obturator and the screw cap after each use.

It should be ensured that all medicated feed is consumed.

Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles. When the occasion arises of any uneaten or partly consumed medicated feed, this feed should be safely discarded and not given to any other animal.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No information available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal 9 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03DX90

4.2 Pharmacodynamics

Altrenogest prevents oestrus and ovulation by inhibiting the release of the gonadotropins LH and FSH from the pituitary. After the end of treatment physiological oestrus (ovulation) occurs after 4-8 days.

4.3 Pharmacokinetics

Altrenogest is well and rapidly absorbed. It is distributed in the organs, muscle, fat, liver and kidney tissue. After 48 hours altrenogest is still present in the blood, but only just above the detection limit. The highest concentrations are found in the liver and kidneys. The liver is the main organ involved in the metabolism of altrenogest and the excretion occurs via the faeces and urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening of the immediate packaging (bottle): 90 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Carton box containing one 540 ml or 1 L aluminium bottle with a low density polyethylene obturator and a polypropylene screw cap. A dosing cup is included with both presentation sizes.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
{To be adjusted nationally.}

The veterinary medicinal product should not enter water courses as altrenogest may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{To be completed nationally.}

7. MARKETING AUTHORISATION NUMBER(S)

{To be completed nationally.}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *{To be completed nationally.}*

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD month YYYY}
{To be completed nationally.}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folliplan, 4 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Altrenogest 4.0 mg

3. PACKAGE SIZE

540 ml
1L

4. TARGET SPECIES

Pigs (sows, nulliparous)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In-feed use

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 90 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle (aluminium) in 1 L and 540 ml presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folliplan, 4 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Altrenogest 4.0 mg

3. TARGET SPECIES

Pigs (sows, nulliparous)

4. ROUTES OF ADMINISTRATION

In-feed use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal 9 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 90 days, by ___/___/___

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Folliplan, 4 mg/ml oral solution for pigs

2. Composition

Each ml contains:

Active substance:
Altrenogest 4.0 mg
Excipients:
Butylhydroxytoluene (E321) 0.07 mg
Butylhydroxyanisole (E320) 0.07 mg

Clear, yellow solution.

3. Target species

Pigs (sows, nulliparous)

4. Indications for use

For the synchronisation and control of oestrus in cycling nulliparous sows.

5. Contraindications

Do not use in male animals.
Do not administer to pregnant sows or those suffering from uterine infection.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special Warnings:
To use only in sexually mature sows who had already presented one oestrus.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product should not be administered by women who are, or maybe pregnant. Women of childbearing age should avoid contact with the veterinary medicinal product.

This veterinary medicinal product should not be handled by:
- persons with known or suspectedprogesterone-dependent tumours
- persons with thrombo-embolic disorders

Avoid contact with the skin and eyes. In case of accidental spillage onto skin it should be washed off immediately with soap and water. In case of accidental contact with the eyes, rinse thoroughly with

water for 15 minutes and seek medical advice immediately and show the package leaflet or the label to the physician.

Personal protective equipment consisting of overalls and gloves should be worn when handling the veterinary medicinal product. This veterinary medicinal product can penetrate latex or other types of porous gloves. Absorption through the skin may be even higher when the area is covered by an occlusive material.

Wash hands after use.

Effects of overexposure: repeated accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache.

Special precautions for the protection of the environment:

When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, because the manure may contain altrenogest which could cause adverse effects in the aquatic environment.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

No data available.

Overdose:

No information available.

Major incompatibilities:

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

7. Adverse events

Pigs (sows, nulliparous):
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

In-feed use.
Add the veterinary medicinal product to the feed immediately before feeding.

5 ml (corresponding to 20 mg altrenogest) per animal during 18 days.

9. Advice on correct administration

Remove the screw cap and the obturator and measure the clinical dose of 5 mL using the dosing cup provided, pour the dose on the feed and close the bottle with the obturator and the screw cap after each use.

It should be ensured that all medicated feed is consumed.

Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles. When the occasion arises of any uneaten or partly consumed medicated feed, this feed should be safely discarded and not given to any other animal.

10. Withdrawal periods

Meat and offal 9 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 this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of the month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as altrenogest may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.>

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number:

Carton box containing one 540 ml or 1 L aluminium bottle with a low density polyethylene obturator and a polypropylene screw cap. A dosing cup is included with both presentation sizes.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:

Manufacturer responsible for batch release:

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

C. Combined Label and Package Leaflet

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Aluminium bottle (540 ml, 1 L)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folliplan, 4 mg/ml oral solution

2. COMPOSITION

Each ml contains:

Active substance:
Altrenogest 4.0 mg
Excipients:
Butylhydroxytoluene (E321) 0.07 mg
Butylhydroxyanisole (E320) 0.07 mg

Clear, yellow solution.

3. PACKAGE SIZE

540 ml
1 L

4. TARGET SPECIES

Pigs (sows, nulliparous)

5. INDICATIONS FOR USE

Indications for use
For the synchronisation and control of oestrus in cycling nulliparous sows.

6. CONTRAINDICATIONS

Contraindications
Do not use in male animals.
Do not administer to pregnant sows or those suffering from uterine infection.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Use only in sexually mature sows who had already presented one oestrus.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product should not be administered by women who are, or maybe pregnant. Women of childbearing age should avoid contact with the veterinary medicinal product.

This veterinary medicinal product should not be handled by:
- persons with known or suspected progesterone-dependent tumours
- persons with thrombo-embolic disorders

Avoid contact with the skin and eyes. In case of accidental spillage onto skin it should be washed off immediately with soap and water. In case of accidental contact with the eyes, rinse thoroughly with water for 15 minutes and seek medical advice immediately and show the package leaflet or the label to the physician.

Personal protective equipment consisting of overalls and gloves should be worn when handling the veterinary medicinal product. This veterinary medicinal product can penetrate latex or other types of porous gloves. Absorption through the skin may be even higher when the area is covered by an occlusive material.

Wash hands after use.

Effects of overexposure: repeated accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache.

Special precautions for the protection of the environment:
When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, because the manure may contain altrenogest which could cause adverse effects in the aquatic environment.

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction:
No data available.

Overdose:
No information available.

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

8. ADVERSE EVENTS

Adverse events

Pigs (sows, nulliparous):

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
In-feed use.
Add the veterinary medicinal product to the feed immediately before feeding.
5 ml (corresponding to 20 mg altrenogest) per animal during 18 days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
Remove the screw cap and the obturator and measure the clinical dose of 5 mL using the dosing cup provided, pour the dose on the feed and close the bottle with the obturator and the screw cap after each use.
It should be ensured that all medicated feed is consumed.
Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles.
When the occasion arises of any uneaten or partly consumed medicated feed, this feed should be safely discarded and not given to any other animal.

11. WITHDRAWAL PERIODS

Withdrawal periods
Meat and offal: 9 days

12. SPECIAL STORAGE PRECAUTIONS

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 this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of the month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
{To be adjusted nationally.}

This veterinary medicinal product should not enter water courses as altrenogest may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.
{< > to be adjusted nationally}

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

MA number:

Pack sizes
Carton box containing one 540 ml or 1 L aluminium bottle with a low density polyethylene obturator and a polypropylene screw cap. A dosing cup is included with both presentation sizes.
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{DD month YYYY}
{< > to be completed nationally}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
{< > to be completed nationally}

Manufacturer responsible for batch release:

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

<Local representatives <and contact details to report suspected adverse reactions>:>
{< > to be completed nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>

{< > to be completed nationally}

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within 90 days, by ___/___/___

21. BATCH NUMBER

Lot {number}