ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagest 4 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:
Altrenogest 4.00 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
Soya-bean oil refined	

A clear colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (nulliparous mature sows).

3.2 Indications for use for each target species

For the synchronisation of oestrus.

3.3 Contraindications

Do not use in boars.
Do not administer to pregnant sows (see section 3.7) 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 gilts that have been in oestrus.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Discard any uneaten medicated feed.
Part-consumed feed must be safely disposed of with other waste feed and not given to any other animals.

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

The veterinary medicinal product should not be administered by pregnant women or women suspected to be pregnant. Women of childbearing age should handle the product with extreme care.
The veterinary medicinal product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

Direct contact with the skin should be avoided. Personal protective equipment consisting of gloves and overalls must be worn when handling the veterinary medicinal product. Porous gloves may let this product pass through. Transcutaneous absorption may be even higher when the area is covered by an occlusive material, such as latex or rubber gloves. Accidental spillage on the skin should be washed off immediately with soap and water. Wash hands after treatment and before meals.
In case of accidental contact with eye, rinse abundantly with water. Seek medical attention.

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.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

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 (nulliparous mature sows):

Undetermined frequency (cannot be estimated from the available data):	Ovarian cyst[1]

[1]Can occur in case of underdosing

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Griseofulvin may alter the effects of altrenogest when administered concurrently with this veterinary medicinal product.

3.9 Administration routes and dosage

Oral use.

20 mg altrenogest per animal (corresponding to 5 ml of the product per animal) per day, for 18 consecutive days. Give immediately after mixing with the feed.
The volume to be administered should be measured with an appropriate dosing device.

Administration:
Animals should be segregated and dosed individually. Add the veterinary medicinal product as a top-dressing to the feed immediately before feeding.

The synchronisation of oestrus should be supervised by a veterinarian. Nulliparous mature sows should be segregated not later than 7 days before treatment. During treatment, animals should not change rooms.
A complete up-take of the medicated feed should be assured.

Most treated gilts will come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

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

No data 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 has a similar action to the natural hormone progesterone. When administered orally, it suppresses the normal sexual cycle, preventing signs of heat and ovulation. Withdrawal then allows the natural hormones to be released again, and animals return to heat in a synchronised fashion.

Altrenogest is a synthetic trienic C21 steroidal progestagen belonging to the 19-nor-testosterone series. It is an orally active progestagen. Altrenogest decreases blood concentrations of the endogenous gonadotrophins, LH and FSH. As a consequence, it induces the regression of all large follicles (> 20-25 mm) and therefore blocks oestrus or ovulation. During the second half of the treatment period with the product, when all large follicles have regressed, there is a peak in FSH concentration which initiates a new wave of follicular growth. End of treatment is followed by a steady rise in LH concentration, which sustains follicular growth and maturation.

4.3 Pharmacokinetics

Altrenogest is rapidly absorbed following oral administration. Altrenogest is extensively metabolised in the liver. Altrenogest is eliminated both via bile in faeces and via 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 the immediate packaging: 60 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

PET bottle with an unremovable plastic shell clipped or co-extruded to the bottle.
The bottle is hermetically closed with a child-proof screw cap equipped by a triseal joint.

Package size:
1 x 450 ml bottle
1 x 900 ml bottle

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.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (same information as for an OUTER PACKAGE)

450 ml PET bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagest 4 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Altrenogest 4.00 mg/ml

3. PACKAGE SIZE

450 ml

4. TARGET SPECIES

Pigs (nulliparous mature sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use as a top-dressing.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 60 days.
Once opened, use by …

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (same information as for an OUTER PACKAGE)

900 ml PET bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagest 4 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Altrenogest 4.00 mg/ml

3. PACKAGE SIZE

900 ml

4. TARGET SPECIES

Pigs (nulliparous mature sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use as a top-dressing.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 60 days.
Once opened, use by …

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Virbagest 4 mg/ml oral solution for pigs

2. Composition

Each ml contains :

Active substance:
Altrenogest 4.00 mg

Excipients:
Butylhydroxytoluene (E321) 0.07 mg
Butylhydroxyanisole (E320) 0.07 mg

A clear colourless to pale yellow solution.

3. Target species

Pigs (nulliparous mature sows).

4. Indications for use

For the synchronisation of oestrus.

5. Contraindications

Do not use in boars.
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.
See section “Special warnings”.

6. Special warnings

Special warnings:
Use only in sexually mature gilts that have been in oestrus.

Special precautions for safe use in the target species:
Discard any uneaten medicated feed.
Part-consumed feed must be safely disposed of with other feed waste and not given to any other animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product should not be administered by pregnant women or women suspected to be pregnant. Women of childbearing age should handle the product with extreme care.

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

Direct contact with the skin should be avoided. Personal protective equipment consisting of gloves and overalls must be worn when handling the veterinary medicinal product. Porous gloves may let this product pass through. Transcutaneous absorption may be even higher when the area is covered by an occlusive material, such as latex or rubber gloves. Accidental spillage on the skin should be washed off immediately with soap and water. Wash hands after treatment and before meals.
In case of accidental contact with eye, rinse abundantly with water. Seek medical attention.

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.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

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:
Griseofulvin may alter the effects of altrenogest when administered concurrently with this veterinary medicinal product.

Overdose:
No data 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 (nulliparous mature sows):

Undetermined frequency (cannot be estimated from the available data):
Ovarian cyst[1]

[1]Can occur in case of underdosing

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

Oral use.
20 mg altrenogest per animal (corresponding to 5 ml of the product per animal) per day, for 18 consecutive days. Give immediately after mixing with the feed.
The volume to be administered should be measured with an appropriate dosing device.

9. Advice on correct administration

Animals should be segregated and dosed individually. Add the veterinary medicinal product as a top-dressing to the feed immediately before feeding.

The synchronisation of oestrus should be supervised by a veterinarian. Nulliparous mature sows should be segregated not later than 7 days before treatment. During treatment, animals should not change rooms.
A complete up-take of the medicated feed should be assured.

Most treated gilts will come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

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 bottle after Exp. The expiry date refers to the last day of that month..

Shelf life after first opening the immediate packaging: 60 days.

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

Package size:
1 x 450 ml bottle or 1 x 900 ml bottle.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
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.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

450 ml or 900 ml PET bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagest 4 mg/ml oral solution for pigs

2. COMPOSITION

Each ml contains :

Active substance:
Altrenogest 4.00 mg

Excipients:
Butylhydroxytoluene (E321) 0.07 mg
Butylhydroxyanisole (E320) 0.07 mg

A clear colourless to pale yellow solution.

3. PACKAGE SIZE

450 ml
900 ml

4. TARGET SPECIES

Pigs (nulliparous mature sows).

5. INDICATIONS FOR USE

Indications for use

For the synchronisation of oestrus.

6. CONTRAINDICATIONS

Contraindications

Do not use in boars.
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.
See section “Special warnings”.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Use only in sexually mature gilts that have been in oestrus.

Special precautions for safe use in the target species:
Discard any uneaten medicated feed.
Part-consumed feed must be safely disposed of with other feed waste and not given to any other animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product should not be administered by pregnant women or women suspected to be pregnant. Women of childbearing age should handle the product with extreme care.
The veterinary medicinal product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

Direct contact with the skin should be avoided. Personal protective equipment consisting of gloves and overalls must be worn when handling the veterinary medicinal product. Porous gloves may let this product pass through. Transcutaneous absorption may be even higher when the area is covered by an occlusive material, such as latex or rubber gloves. Accidental spillage on the skin should be washed off immediately with soap and water. Wash hands after treatment and before meals.
In case of accidental contact with eye, rinse abundantly with water. Seek medical attention.

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.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

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:
Griseofulvin may alter the effects of altrenogest when administered concurrently with this veterinary medicinal product.

Overdose:
No data 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 (nulliparous mature sows):

Undetermined frequency (cannot be estimated from the available data):
Ovarian cyst[1]

[1]Can occur in case of underdosing

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

Oral use.
20 mg altrenogest per animal (corresponding to 5 ml of the product per animal) per day, for 18 consecutive days. Give immediately after mixing with the feed.
The volume to be administered should be measured with an appropriate dosing device.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Animals should be segregated and dosed individually. Add the veterinary medicinal product as a top-dressing to the feed immediately before feeding.

The synchronisation of oestrus should be supervised by a veterinarian. Nulliparous mature sows should be segregated not later than 7 days before treatment. During treatment, animals should not change rooms.
A complete up-take of the medicated feed should be assured.

Most treated gilts will come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

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 bottle after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
1 x 450 ml bottle or 1 x 900 ml bottle.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
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 listed below.

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 60 days.
Once opened, use by …

Shelf life after first opening the immediate packaging: 60 days.

21. BATCH NUMBER

Lot {number}