[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suifertil 4 mg/ml oral solution for pigs (AT, BE, BG, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SK, UK(NI))
Synchroplan 4 mg/ml solution buvable pour porcins (FR)

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**
Butylhydroxyanisole (E320)	0.07 mg
Butylhydroxytoluene (E321)	0.07 mg
Soya-bean oil	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (nulliparous mature sows).

3.2 Indications for use for each target species

Synchronisation of oestrous in nulliparous mature sows.

3.3 Contraindications

Do not use in boars.
Do not use in 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

To use only in nulliparous mature sows that have had at least one oestrous cycle.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The medicated feed is to be given to the nulliparous mature sows, once the veterinary medicinal product has been added.
Part consumed feed must be safely disposed and not given to any other animals.

Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles.

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

Direct contact with the skin should be avoided. Personal protective clothing (gloves and overalls) must be worn when handling the veterinary medicinal product. Porous gloves may let this veterinary medicinal product pass through to the skin. If the veterinary medicinal product makes contact with the skin underneath the glove, occlusive materials such as latex or rubber in gloves may enhance transcutaneous absorption of the veterinary medicinal product.

Accidental spillage on the skin or eyes should be washed off immediately with plenty of water.

Wash hands after treatment and before meals.

Pregnant women and women of childbearing age should avoid contact with the veterinary medicinal product or should exercise extreme caution when handling this veterinary medicinal product.

People suffering from progesterone dependent tumours (known or suspected) or from thromboembolic disorders should not use the veterinary medicinal product.

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

Over-exposure effects: Accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache. In case of over-exposure, seek medical advice.

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

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not administer to pregnant and lactating sows.

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

Top-dressing use.

20 mg of altrenogest / animal, i.e. 5 ml per animal once a day for 18 consecutive days.

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

Most treated nulliparous mature sows will be come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

The veterinary medicinal product should be administered with the Suifertil pump dosing system only.

Administration with the dosing system:
To prime the doser:

- put the bottle in a vertical position
- slowly pull the trigger until a drop pearls at the tip of the nozzle.

Then, the doser delivers 5 ml dose for each complete activation of the trigger. The doser should remain on the bottle for the whole veterinary medicinal product in-use period, and the cap system should be used for any storage between treatments.

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

None known.

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 is a synthetic progestogen belonging to the 19-nortestosterone family. It is active by the oral route. Altrenogest acts by reducing the blood concentrations of the endogenous gonadotrophins LH and FSH in the blood. The low levels of gonadotrophins induce regression of the large follicles (> 5 mm) present at the start of treatment and prevent the growth of follicles larger than 3 mm, thus resulting in the absence of oestrous and ovulation during treatment. Once the treatment has stopped there is a regular increase in the concentration of LH allowing follicular growth and maturation.

4.3 Pharmacokinetics

Altrenogest is rapidly absorbed after oral administration. Altrenogest is mainly metabolised in the liver. Altrenogest is excreted via the bile in the faeces and, in variable proportion, in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, the 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: 5 years.
Shelf-life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

Keep the bottle in upright position after first use.

5.4 Nature and composition of immediate packaging

Aluminium bottle with inner protective lacquer, and screw cap (PP) with washer (LDPE/Al) and plug (LDPE).

Package size:
1 x 1000 ml bottle

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 this 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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 OUTER PACKAGE

{Label, bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suifertil 4 mg/ml oral solution (AT, BE, BG, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SK, UK(NI))

Synchroplan 4 mg/ml solution buvable pour porcins (FR)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Altrenogest 4.00 mg

3. PACKAGE SIZE

1000 ml

4. TARGET SPECIES

Pigs (nulliparous mature sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Top -dressing use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 9 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within: 3 months.
Once opened, use by: . . . .

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in upright position after first use.

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

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suifertil 4 mg/ml oral solution for pigs (AT, BE, BG, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SK, UK(NI))
Synchroplan 4 mg/ml solution buvable pour porcins (FR)

2. Composition

Each ml contains:

Active substance:
Altrenogest 4.00 mg

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

Clear, yellow solution.

3. Target species

Pigs (nulliparous mature sows).

4. Indications for use

Synchronisation of oestrous in nulliparous mature sows.

5. Contraindications

Do not use in boars.
Do not use in pregnant sows (see section "Pregnancy and lactation") or to 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 nulliparous mature sows that have had at least one oestrous cycle.

Special precautions for safe use in the target species:

The medicated feed is to be given to the nulliparous mature sows, once the veterinary medicinal product has been added.
Part consumed feed must be safely disposed and not given to any other animals.

Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct contact with the skin should be avoided. Personal protective clothing (gloves and overalls) must be worn when handling the veterinary medicinal product. Porous gloves may let this veterinary medicinal product pass through to the skin. If the veterinary medicinal product makes contact with the skin underneath the glove, occlusive materials such as latex or rubber in gloves may enhance transcutaneous absorption of the veterinary medicinal product.

Accidental spillage on the skin or eyes should be washed off immediately with plenty of water.

Wash hands after treatment and before meals.

Pregnant women and women of childbearing age should avoid contact with the veterinary medicinal product or should exercise extreme caution when handling this veterinary medicinal product.

People suffering from progesterone dependent tumours (known or suspected) or from thromboembolic disorders should not use the veterinary medicinal product.

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

Over-exposure effects: Accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache. In case of over-exposure, seek medical advice.

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 administer to pregnant and lactating sows.

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:
None known.

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

7. Adverse events

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 its local representative 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

Top-dressing use.

20 mg of altrenogest / animal, i.e. 5 ml per animal once a day for 18 consecutive days.

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

Most treated nulliparous mature sows will be come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

9. Advice on correct administration

The veterinary medicinal product should be administered with the Suifertil pump dosing system only.

Administration with the dosing system:
To prime the doser:

- put the bottle in a vertical position
- slowly pull the trigger until a drop pearls at the tip of the nozzle.

Then, the doser delivers 5 ml dose for each complete activation of the trigger. The doser should remain on the bottle for the whole veterinary medicinal product in-use period, and the cap system should be used for any storage between treatments.

10. Withdrawal periods

Meat and offal: 9 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the bottle in upright position after first use.
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 that month.
Shelf-life after first opening the immediate packaging: 3 months.

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 this 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

XXX

Pack size: 1000 ml.

15. Date on which the package leaflet was last revised

{MM/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 events:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany
Tel: +49 2536 3302 0

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industria Italiana Integratori TREI S.p.A.
Via Affarosa 4
42010 Rio Saliceto
Italy

Local representatives and contact details to report suspected adverse events:

17. Other information

Suifertil 4 mg/ml does not contain any preservatives.

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

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suifertil 4 mg/ml oral solution for pigs (AT, BE, BG, CZ, DE, DK, ES, HU, IE, IT, NL, PL, PT, RO, SK, UK(NI))

Synchroplan 4 mg/ml solution buvable pour porcins (FR)

2. COMPOSITION

Each ml contains:

Active substance:
Altrenogest 4.00 mg

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

Clear, yellow solution.

3. PACKAGE SIZE

1000 ml

4. TARGET SPECIES

Pigs (nulliparous mature sows).

5. INDICATIONS FOR USE

Indications for use

Synchronisation of oestrous in nulliparous mature sows.

6. CONTRAINDICATIONS

Contraindications

Do not use in boars.
Do not use in pregnant sows (see section "Pregnancy and lactation") or to 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

Special warnings:
To use only in nulliparous mature sows that have had at least one oestrous cycle.

Special precautions for safe use in the target species:
The medicated feed is to be given to the nulliparous mature sows, once the veterinary medicinal product has been added.
Part consumed feed must be safely disposed and not given to any other animals.

Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles.

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

Direct contact with the skin should be avoided. Personal protective clothing (gloves and overalls) must be worn when handling the veterinary medicinal product. Porous gloves may let this veterinary medicinal product pass through to the skin. If the veterinary medicinal product makes contact with the skin underneath the glove, occlusive materials such as latex or rubber in gloves may enhance transcutaneous absorption of the veterinary medicinal product.

Accidental spillage on the skin or eyes should be washed off immediately with plenty of water.

Wash hands after treatment and before meals.

Pregnant women and women of childbearing age should avoid contact with the veterinary medicinal product or should exercise extreme caution when handling this veterinary medicinal product.

People suffering from progesterone dependent tumours (known or suspected) or from thromboembolic disorders should not use the veterinary medicinal product.

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

Over-exposure effects: Accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache. In case of over-exposure, seek medical advice.

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 administer to pregnant and lactating sows.

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:
None known.

Major incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

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 its local representative 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

Top-dressing use.

20 mg of altrenogest / animal, i.e. 5 ml per animal once a day for 18 consecutive days.

Animals should be segregated and dosed individually.

Add the veterinary medicinal product as a top dressing to the feed immediately before feeding. Discard any uneaten medicated feed.

Most treated nulliparous mature sows will be come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

The veterinary medicinal product should be administered with the Suifertil pump dosing system only.

Administration with the dosing system:
To prime the doser:

- put the bottle in a vertical position
- slowly pull the trigger until a drop pearls at the tip of the nozzle.

Then, the doser delivers 5 ml dose for each complete activation of the trigger. The doser should remain on the bottle for the whole veterinary medicinal product in-use period, and the cap system should be used for any storage between treatments.

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.

Keep the bottle in upright position after first use.

Do not use this veterinary medicinal product after the expiry date which is stated on this label 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 this 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

EU/0/00/000/000

Pack sizes

1000 ml

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 (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

aniMedica GmbH

Im Südfeld 9
48308 Senden-Bösensell
GermanyTel: +49 2536 3302 0

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industria Italiana Integratori TREI S.p.A.
Via Affarosa 4
42010 Rio Saliceto
Italy

Local representatives and contact details to report suspected adverse events:

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

18. OTHER INFORMATION

Other information

Suifertil 4 mg/ml does not contain any preservatives.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Once opened, use within: 3 months.Once opened, use by: ……..

21. BATCH NUMBER

Lot {number}