1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suifertil 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**
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

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/021/001

8. DATE OF FIRST AUTHORISATION

16/03/2016

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

13/10/2025

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).