SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suifertil 4 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Altrenogest 4.00 mg

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (nulliparous mature sows).

4.2 Indications for use, specifying the target species

Synchronisation of oestrous in nulliparous mature sows.

4.3 Contraindications

Do not use in boars.
Do not administer to pregnant sows (see section 4.7) or those suffering from uterine infection.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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

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 product. Porous gloves may let this product pass through to the skin. If the product makes contact with the skin underneath the glove, occlusive materials such as latex or rubber in gloves may enhance transcutaneous absorption of the 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 product or should exercise extreme caution when handling this product.

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

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

Direct contact with the skin should therefore be avoided.

Other precautions regarding impact on 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant and lactating sows.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

For oral use as a top-dressing.

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 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 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 product in-use period, and the cap system should be used for any storage between treatments.

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

None known.

4.11 Withdrawal period(s)

Meat and offal: 9 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Sex hormones and modulators of the genital system, progestagens
ATCvet code:
QG03DX90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Soya-bean oil

6.2 Major incompatibilities

6.3 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.

6.4. Special precautions for storage

Keep the bottle in upright position after first use.

6.5 Nature and composition of immediate packaging

1000 ml in an aluminium bottle with inner protective lacquer, and screw cap (PP) with washer (LDPE/Al) and plug (LDPE).

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

Suifertil - The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 24745/4019

9. DATE OF FIRST AUTHORISATION

23 December 2013

10. DATE OF REVISION OF THE TEXT

November 2017

Approved: 15/11/2017