# Combined LABEL and PACKAGE LEAFLET

Suifertil 4 mg/ml oral solution for pigs

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

**Marketing authorisation holder and manufacturer responsible for batch release:**
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany
**Distributor**
FORTE Healthcare Limited
Cougar Lane
Naul
Co. Dublin
Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suifertil 4 mg/ml oral solution for pigs
Altrenogest

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

1 ml contains:

**Active substance:**
Altrenogest 4.00 mg

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

Clear, yellow solution.

## 4. INDICATION(S)

Synchronisation of oestrous in nulliparous mature sows.

## 5. CONTRAINDICATIONS

Do not use in boars.
Do not administer to 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. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Pigs (nulliparous mature sows).

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 18$^{th}$ consecutive day of treatment.

## 9. ADVICE ON CORRECT ADMINISTRATION

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.

## 10. WITHDRAWAL PERIOD(S)

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 this label after EXP. The expiry date refers to the last day of that month

## 12. SPECIAL WARNING(S)

**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.

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

**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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{MM/YYYY}

## 15. OTHER INFORMATION

Package size: 1000 ml

EXP {month/year}

Once opened, use by: ……..
Shelf-life after first opening the immediate packaging: 3 months.

For animal treatment only.

To be supplied only on veterinary prescription.

<Batch> <Lot> <BN> {number}

Marketing Authorisation Number: Vm 24745/4019

Only if local representative is mentioned:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Suifertil 4 mg/ml does not contain any preservatives.

**Approved: 15/11/2017**