

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Altresyn 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	
Nitrogen	

Clear, pale yellow, odourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sexually mature gilts and sows).

3.2 Indications for use for each target species

For the synchronisation of oestrus.

3.3 Contraindications

Do not administer to animals suffering from uterine infection. Do not administer to male animals. See section 3.7.

3.4 Special warnings

None

3.5 Special precautions for use

Special precautions for safe use in the target species:

Add the veterinary medicinal product as top-dressing to the feed immediately before feeding or administer directly by drenching.

Discard any uneaten medicated feed

To use only in sexually mature gilts who had already presented first oestrus.

Part consumed feed must be safely disposed of and not given to any other animal.

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.

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. Direct contact with the skin should therefore be avoided.

In case of over-exposure, seek medical advice immediately and show the package leaflet or the label to the physician.

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 : 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 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 in pregnant or lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use.

Sexually mature gilts:

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

Sows:

20 mg altrenogest / animal, i.e. 5 ml per animal once a day for 3 to 14 consecutive days.

For 540 and 1080 ml presentations:

The medicinal veterinary medicinal product should be administered with the Altresyn doser only.

To prime the doser:

- put the bottle in an horizontal position, the nozzle of the doser directed up-wards
- slowly press 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. For the regular administration hold the vial vertically upside-down. The doser should remain on the bottle for the whole veterinary medicinal product in-use period, and the lock system should be used for any storage between treatments.

For the 360 ml presentation:

Press and release the metering pump to deliver one 5 ml dose. Do not shake before use to avoid mixing the solution with the nitrogen included in the pressurised container.

Animals should be segregated and dosed individually. Add the veterinary medicinal product as a top dressing to the feed immediately before feeding or administer directly by drenching. Add to the surface of the feed immediately before feeding and control the consumption of the dose. The Veterinary Medicinal Product should be administered at the same time every day.

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

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 progestagen belonging to the 19-nor-testosterone family. This progestagen is active by oral route. Altrenogest acts by decreasing plasma concentrations of endogenous gonadotrophin hormones (LH and FSH). Low gonadotrophin concentrations induce the formation of large follicles (> 5 mm) and do not allow the growth of follicles greater than 3 mm, leading then to an absence of oestrus and ovulation during treatment. The end of treatment is followed by a regular increase in LH plasma concentration allowing follicular growth and maturation. Then, animals return to heat in a synchronised way.

A multicentre field study evaluated the efficacy of altrenogest in synchronizing the first oestrus onset of postponed primiparous sows, involving 414 sows of various breeds coming from five commercial herds and different production systems. The sows were treated orally at the dose rate of 20 mg of altrenogest per animal for either 7 or 14 days starting the day of weaning and were compared to a negative control group. Results showed that altrenogest effectively postponed and synchronized the first oestrus onset within a week after treatment in 91% and 84% of sows for the 7-day and 14-day treatment groups, respectively, without impacting reproductive performance or safety.

Another multicentre clinical trial was conducted to evaluate the efficacy of altrenogest for the oestrus synchronisation in 431 multiparous sows of various breed coming from five commercial herds and different production systems. Sows were given orally a daily dose of 20 mg of altrenogest per animal for either 7 or 14 consecutive days starting at weaning and were compared to negative control groups under standard management. Results showed that altrenogest effectively postponed and synchronised the oestrus within a week after the end of treatment in 89.0% (89/100) and 88.6% (93/105) of the sows for the 7-day and 14-day treatment groups, respectively, without impacting reproductive performance or safety. No negative impact on reproductive performance or safety was observed. These results confirmed the efficacy of altrenogest for 7 and 14 consecutive days in postponing and synchronising oestrus compared to standard weaning procedures in multiparous sows.

A third, monocentric, field clinical trial evaluated the efficacy of altrenogest for the control of oestrus onset timing in 36 sows. Sows were treated orally with 20 mg of altrenogest per animal for 3 consecutive days starting the day of weaning and were compared to a negative control group under standard management. Results showed that altrenogest effectively postponed the first oestrus onset within a week after the end of treatment in 94.7% (18/19) of the sows without impacting the safety. These results showed the efficacy of altrenogest for 3 consecutive days in postponing the timing of 1st oestrus onset for the duration of the treatment compared to standard procedures in sows.

4.3 Pharmacokinetics

Altrenogest is rapidly absorbed following oral administration, with peak plasma concentrations being reached between 1 and 4 hours after treatment. Altrenogest is mainly metabolised in the liver and eliminated by biliary excretion. Half life of elimination is estimated to be around 14 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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 (for 540 and 1080 ml presentations): 2 months.

5.3 Special precautions for storage

360 ml pressurized container: Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use.

540 and 1080 ml: no special precautions for storage.

5.4 Nature and composition of immediate packaging

Nature of 360 ml container:

"Pressurised aluminium container with a metering pump."

Nature of 540 and 1080 ml containers:

Aluminium container closed with a polyethylene plug and a polypropylene screw cap.

Package sizes:

Carton of 1 container of 360 ml
Carton of 3 containers of 360 ml
540 ml container
1080 ml container

Not all pack sizes may be marketed.

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

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater.

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

Ceva Sante Animale

7. MARKETING AUTHORISATION NUMBER

Vm 14966/5045

8. DATE OF FIRST AUTHORISATION

17 February 2009

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 16 October 2025