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
Butylhydroxytoluène (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 weaned primiparous sows).

3.2 Indications for usefor 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:
Discard any uneaten medicated feed.
For use only in sexually mature gilts that have had at least one oestrous cycle, and in primiparous sows at the time of weaning.
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 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.
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 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 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.

Weaned primiparous 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 veterinary medicinal product should be administered with the Altresyn doser only.
To prime the doser:
- put the bottle in a horizontal position, with the nozzle of the doser directed upwards
- slowly press the trigger until a drop pearls at the tip of the nozzle.

The doser delivers 5 ml dose for each complete activation of the trigger. For regular administration hold the vial vertically upside-down. The doser should remain on the bottle for the whole in-use period, and the lock system should be used during 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 dosed individually. Add the veterinary medicinal product as a top dressing to the surface of the feed immediately before feeding and control the consumption of the dose. Alternatively, the product can be drenched directly into the animal's mouth by pressing the dispenser pump with the bottle upside down.
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 regression of large follicles (> 5 mm) and do not allow the growth of follicles greater than 3 mm, leading then to an absence of œstrus 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 clinical trial evaluated the efficacy of altrenogest for the oestrus synchronisation in 414 primiparous 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% (81/89) and 84% (89/106) of sows for the 7-day and 14-day treatment groups, respectively, without impacting reproductive performance or safety. These results showed the efficacy of altrenogest in postponing and synchronising oestrus compared to standard weaning procedures, where the onset of oestrus within a week was observed in 83.8% (75/90) and 78.3% (83/106) of sows in the negative control groups

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 size:
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 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

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/010/001

8. DATE OF FIRST AUTHORISATION

06/02/2009

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

27/09/2024

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*).