

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:

Butylhydroxyanisole (E320)0.07 mg

Butylhydroxytoluène (E321).....0.07 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution

Clear, pale yellow, odourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sow, nullipar and primipar).

4.2 Indications for use, specifying the target species

For the synchronisation of oestrus .

4.3 Contraindications

Do not administer to animals suffering from uterine infection. Do not administer to male animals.
See section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Add the veterinary medicinal product directly by drenching or to the feed immediately before feeding. 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.

Other precautions

Not applicable

4.6 Adverse reactions (frequency and seriousness)

Pig

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.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

For oral use as a top-dressing.

Sow, nullipar:

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

Sow, primipar:

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 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 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 product directly by drenching or as a top dressing to the feed. Add to the surface of the feed immediately before feeding and control the consumption of the dose. Product should be administered at the same/similar time every day.

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

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

None known.

4.11 Withdrawal period(s)

Meat and offal: 9 days

5. PHARMACOLOGICAL

Pharmacotherapeutic group: Sex hormones and modulators of the genital system.
ATC vet code: QG03DX90.

5.1 Pharmacodynamic properties

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 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluène (E321)
Soya bean oil
Nitrogen

6.2 Major incompatibilities

None known.

6.3 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.

6.4 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.

6.5 Nature and composition of immediate packaging

360 ml Pressurised aluminium container with a metering pump.

540 and 1080 ml Aluminium container closed with a polyethylene plug and a polypropylene screw cap.

Package size:

Cardboard Carton of 1 pressurised container of 360 ml

Cardboard Carton of 3 pressurised containers of 360 ml

540 ml Aluminium container

1080 ml Aluminium container

Not all pack sizes may be marketed.

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

Altresyn should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5071

9. DATE OF FIRST AUTHORISATION

17 February 2009

10. DATE OF REVISION OF THE TEXT

September 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.