

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Altresyn 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

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 (sexually mature gilts).

4.2 Indications for use, specifying the target species

For the synchronisation of oestrus in sexually mature gilts.

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 to the feed immediately before feeding. Discard any uneaten medicated feed

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

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 use in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral use as a top-dressing.

20 mg altrenogest / animal, i.e. 5 ml per animal once a day for 18 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 as a top dressing to the feed. Add to the surface of the feed immediately before feeding.

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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones and modulators of the genital system.

ATCvet 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 regression 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.

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**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.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

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 Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 February 2009

Date of last renewal: 16 December 2011

10 DATE OF REVISION OF THE TEXT

April 2019