

## **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

Butylhydroxytoluene (E321).....0.07 mg

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Oral solution

Clear, pale yellow, odourless solution.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Pigs (sexually mature gilts and weaned primiparous 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 safe use in the target species

#### Special precautions for use in animals

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.

#### Pregnancy and lactation:

Do not use in pregnant or lactating animals.

#### Interactions with other medicinal products and other forms of interaction:

None known.

Overdose: None known.

Major incompatibilities: None known.

### 3.6 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.

### **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 Amount(s) to be administered and administration route**

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:

Thecinal 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.

### **4.11 Withdrawal period(s)**

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.

### **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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Butylhydroxyanisole (E320)  
Butylhydroxytoluene (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  
HP10 0HH

**8. MARKETING AUTHORISATION NUMBER**

Vm 15052/5071

**9. DATE OF FIRST AUTHORISATION**

17 February 2009

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

September 2024

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

*Gavin Hall*  
Approved: 06 February 2025