

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard boxes : 360 ml and 3 x 360 ml**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Altresyn 4 mg/ml oral solution

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 ml contains 4 mg of altrenogest.

### **3. PACKAGE SIZE**

360 ml

3 x 360 ml

### **4. TARGET SPECIES**

Pigs (sow, nullipar and primipar).

### **5. INDICATION(S)**

### **6. ROUTES OF ADMINISTRATION**

Oral use.

Do not shake before use to avoid mixing the solution with the nitrogen included in the pressurised container.

### **7. WITHDRAWAL PERIOD(S)**

Withdrawal period:

Meat and offal: 9 days.

### **8. EXPIRY DATE**

Exp: {mm/yyyy}

### **9. SPECIAL STORAGE PRECAUTIONS**

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

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**



**14. MARKETING AUTHORISATION NUMBERS**

Vm 15052/5071

**15. BATCH NUMBER**

Lot: {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

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.

**17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V Veterinary medicinal product subject to prescription.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

Vial of 360 ml

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Altresyn 4 mg/ml oral solution

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 ml contains 4 mg of altrenogest.

**3. TARGET SPECIES**

Pigs (sow, nullipar and primipar)

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: 9 days

**6. EXPIRY DATE**

Exp. {mm/yyyy}

**7. SPECIAL STORAGE PRECAUTIONS**

Keep the container in the outer carton.

Protect from sunlight and do not expose to temperatures exceeding 50 °C.

Do not pierce or burn, even after use.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**



**9. BATCH NUMBER**

Lot {number}

**10. SPECIAL WARNING(S), IF NECESSARY**

**11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet

**12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only

Veterinary medicinal product subject to prescription

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet**  
**540 ml and 1080 ml containers**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Altresyn 4 mg/ml oral solution for pigs.

**2. COMPOSITION**

1 ml contains:

Active substance: Altrenogest: 4mg

Excipients: Butylhydroxyanisole (E320): 0.07 mg butylhydroxytoluene (E321): 0.07 mg

Clear, pale yellow, odourless solution

**3. PACKAGE SIZE**

**4. TARGET SPECIES**

Pigs (sow, nullipar and primapar).

**5. INDICATIONS FOR USE**

For the synchronisation of oestrus .

**6. CONTRAINDICATIONS**

Do not administer to animals suffering from uterine infection.

Do not administer to male animals.

See section “ Use during pregnancy, lactation and lay”.

**7. SPECIAL WARNINGS**

None.

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.

#### Use during pregnancy, lactation or lay

Do not use in pregnant or lactating animals.

#### Interaction with other medicinal products and other forms of interaction

None known.

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

None known.

#### Major incompatibilities:

None known.

## **8. ADVERSE REACTIONS**

Pigs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## **9. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

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.

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

## **10. ADVICE ON CORRECT ADMINISTRATION**

Press and release the metering pump to deliver one 5 ml dose.

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.

Do not shake before use to avoid mixing the solution with the nitrogen included in the pressurised container.

## **11. WITHDRAWAL PERIODS**

Meat and offal: 9 days

## **12. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the label after Exp. The expiry date refers to the last day of that month.

## **13. SPECIAL PRECAUTIONS FOR DISPOSAL**

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 product or waste material derived from the product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

## **14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

POM-V Veterinary medicinal product subject to prescription.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5071

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.

## 16. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

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

## 17. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

Tel: +800 35 22 11 51

E-mail: [pharmacovigilance@ceva.com](mailto:pharmacovigilance@ceva.com)

Manufacturer responsible for batch release:

Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

## 18. OTHER INFORMATION

## 19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.



**20. EXPIRY DATE**

EXP: {mm/yyyy}

Once opened use within 2 months.

**21. BATCH NUMBER**

Lot: {number}

**22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**