

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

**Cardboard box : 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 (sexually mature gilts and sows).

### **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**

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**

Ceva Sante Animale

**14. MARKETING AUTHORISATION NUMBERS**

Vm 14966/5045

**15. BATCH NUMBER**

Lot

**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 SUBSTANCES**

1 ml contains 4 mg of altrenogest.

**3. TARGET SPECIES**

Pigs (sexually mature gilts and sows)

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

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**

Ceva Sante Animale

**9. BATCH NUMBER**

Lot {number}

**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 (sexually mature gilts and sows).

**5. INDICATIONS FOR USE**

**Indications for use**

For the synchronisation of oestrus .

**6. CONTRAINDICATIONS**

**Contraindications**

Do not administer to animals suffering from uterine infection.

Do not administer to male animals.

See section “ Use during pregnancy, lactation”.

**7. SPECIAL WARNINGS**

**Special warnings**

Special warnings:

None.

Special precautions for safe use in the target species:

Add the veterinary medicinal product as top-dressing to the feed immediately before feeding or administer directly by drenching.

Discard any uneaten medicated feed

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

## **8. ADVERSE EVENTS**

### **Adverse events**

Pigs: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 <or the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system at: Website:

<https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

### **Dosage for each species, routes and method of administration**

For oral use

Sexually mature gilts:

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

Sows:

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**

### **Advice on correct administration**

The veterinary medicinal product should be administered with the Altresyn doser only.

To prime the doser:

1. put the bottle in a horizontal position, the nozzle of the doser directed up-wards
2. 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 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.

Animals should be segregated and dosed individually. Add the veterinary medicinal 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/similar time every day.

## **11. WITHDRAWAL PERIODS**

### **Withdrawal periods**

Meat and offal: 9 days

## **12. SPECIAL STORAGE PRECAUTIONS**

### **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**

### **Special precautions for disposal**

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

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

### **Classification of veterinary medicinal products**

POM-V 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).

## **15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 14966/5045

### **Pack sizes**

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**

### **Contact details**

#### Marketing authorisation holder:

Ceva Sante Animale  
8 rue de Logrono  
33500 Libourne  
France

#### 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. 01628 334056  
email [technicalandpvuk-group@ceva.com](mailto:technicalandpvuk-group@ceva.com)

#### Manufacturer responsible for batch release:

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

## **18. OTHER INFORMATION**

### **Other information**

POM-V
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## **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}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Altresyn 4 mg/ml oral solution for pigs.

#### **2. Composition**

Each ml contains:

**Active substance:**

Altrenogest: 4 mg

**Excipients:**

0.07 mg of bButylhydroxyanisole (E320): 0.07 mg. and 0.07 mg of

bButylhydroxytoluène (E321): 0.07 mg

Clear, pale yellow, odourless solution

#### **3. Target species**

Pigs (sexually mature gilts and sows).

#### **4. Indications for use**

For the synchronization of oestrus.

#### **5. Contraindications**

Do not administer to animals suffering from uterine infection.

Do not administer to male animals.

See section "Pregnancy and lactation".

#### **6. Special warnings**

None

#### **Special precautions for safe use in the target species:**

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.

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

None known.

#### Overdose:

None known

#### Major incompatibilities:

None known

### **7. Adverse events**

**Pigs:** None known

Reporting adverse events is important. It allows continuous safety monitoring of a 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

### **8. Dosage for each species, routes and method of administration**

For oral use.

Sexually mature gilts:

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

Sows:

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.

## **9. 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 veterinary medicinal product as a top dressing to the feed immediately before feeding or administer directly by drenching using the metering pump. 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.

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

## **10. Withdrawal periods**

**Pigs:**

Meat and offal: 9 days

## **11. 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.

## **12. Special precautions for disposal**

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. 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).

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 14966/5045

### **Pack sizes**

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.

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Wooburn Green  
High Wycombe  
Buckinghamshire  
HP10 0HH  
United Kingdom  
Tel. 01628 334056  
email [technicalandpvuk-group@ceva.com](mailto:technicalandpvuk-group@ceva.com)

### Manufacturer responsible for batch release:

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

**17. Other information**

POM-V

Veterinary Medicinal product subject to prescription  
For animal treatment only

*Gavin Hall*  
Approved: 16 October 2025