

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**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 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 weaned primiparous 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 PERIODS**

**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 15052/3036

**15. BATCH NUMBER**

Lot: {number}

**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 weaned primiparous sows).

**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**

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}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE 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 4 mg of altrenogest, 0.07 mg of butylhydroxyanisole (E320) and 0.07 mg of butylhydroxytoluène (E321)  
Clear, pale yellow, odourless solution

**3. PACKAGE SIZE**

540 ml  
1080 ml

**4. TARGET SPECIES**

Pigs (sexually mature gilts and weaned primiparous 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 "Pregnancy and lactation".

**7. SPECIAL WARNINGS**

Special warnings:

None.

Special precautions for safe use in the target species:

Discard any uneaten medicated feed. For use only in sexually mature gilts that have had at least one oestrous cycle, and in primiparous sows at the time of weaning.

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 veterinary medicinal product.

Porous gloves may let this veterinary medicinal product pass through to the skin. If the veterinary medicinal product makes contact with the skin underneath the glove, occlusive materials such as latex or rubber in gloves may enhance transcutaneous absorption of the veterinary medicinal 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 veterinary medicinal product or should exercise extreme caution when handling this veterinary medicinal product.

People suffering from progesterone dependent tumours (known or suspected) or from thromboembolic disorders should not use the veterinary medicinal 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 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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system:  
{national system details}

## 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.

#### Weaned, primiparous 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, with the nozzle of the doser directed up-wards
2. slowly press the trigger until a drop pearls at the tip of the nozzle.

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 in-use period, and the lock system should be used during storage between treatments.

Animals should be dosed individually. Add the veterinary medicinal product as a top dressing to the surface of the feed immediately before feeding and control the consumption of the dose. Alternatively, the product can be drenched directly into the animal's mouth by pressing the dispenser pump with the bottle upside down.

The veterinary medicinal product should be administered at the same 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.

This veterinary medicinal product does not require any special storage conditions.



### 13. SPECIAL PRECAUTIONS FOR DISPOSAL

#### Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

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 or pharmacist how to dispose of medicines no longer required.

### 14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

#### Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(<https://medicines.health.europa.eu/veterinary>)

### 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

#### 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.

Vm 15052/3036

### 16. PID LINKS (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 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:

Once opened, use within 2 months, by \_\_\_/\_\_\_/\_\_\_

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

## 21. MANUFACTURER’S BATCH NUMBER

Lot: {number}

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET**  
**(for carton of 1 container of 360 ml and Carton of 3 containers of 360 ml)**

**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: Butylhydroxyanisole (E320): 0.07 mg. Butylhydroxytoluène (E321): 0.07 mg

Clear, pale yellow, odourless solution

**3. Target species**

Pigs (sexually mature gilts and weaned primiparous sows).

**4. Indications for use**

For the synchronisation 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:

Discard any uneaten medicated feed. For use only in sexually mature gilts that have had at least one oestrous cycle, and in primiparous sows at the time of weaning.

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 the animals:

Direct contact with the skin should be avoided. Personal protective clothing (gloves and overalls) must be worn when handling the veterinary medicinal product. Porous gloves may let this veterinary medicinal product pass through to the skin. If the veterinary medicinal product makes contact with the skin underneath the glove, occlusive materials such as latex or rubber in gloves may enhance transcutaneous absorption of the veterinary medicinal 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 veterinary medicinal product or should exercise extreme caution when handling this veterinary medicinal product.

People suffering from progesterone dependent tumours (known or suspected) or from thromboembolic disorders should not use the veterinary medicinal 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.

## **7. Adverse events**

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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

{national system details}

## **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.

Weaned, primiparous 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 dosed individually. Add the veterinary medicinal product as a top dressing to the surface of the feed immediately before feeding and control the consumption of the dose. Alternatively, the product can be drenched directly into the animal's mouth by pressing the dispenser pump with the bottle upside down. 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**

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

## **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 or household waste.  
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 or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.  
Detailed information on this veterinary medicinal product is available in the Union Product Database  
(<https://medicines.health.europa.eu/veterinary>)

#### **14. Marketing authorisation numbers and pack sizes**

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.

Vm 15052/3036

#### **15. PID LINKS (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).

#### **16. 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

#### **17. Other information**