

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 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

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/3044

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 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

Ceva Sante Animale

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 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 and multiparous 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:

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

e-mail: 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.

20 mg altrenogest / animal, i.e. 5 ml per animal once a day

Treatment duration:

Sexually mature gilts: 18 consecutive days.

Weaned primiparous sows: 3 to 14 consecutive days.

Weaned multiparous sows: 7 consecutive days.

In weaned sows, the treatment should start as closely as possible after weaning.

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

Vm 14966/3044

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.

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.

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: +800 35 22 11 51

E-mail: 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 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 and multiparous 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.

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

For oral use.

20 mg altrenogest / animal, i.e. 5 ml per animal once a day.

Treatment duration:

Sexually mature gilts: 18 consecutive days.

Weaned primiparous sows: 3 to 14 consecutive days.

Weaned multiparous sows: 7 consecutive days.

In weaned sows, the treatment should start as closely as possible after weaning.

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.

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14. Marketing authorisation numbers and pack sizes

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Buckinghamshire
HP10 0HH
United Kingdom

Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

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

17. Other information

POM-V

Gavin Hall
Approved: 18 March 2026