

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Altresyn 4 mg/ml oral solution for pigs
Altrenogest

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 4 mg of altrenogest.

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

360 ml
3 x 360 ml

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 9 days.

9. 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.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Not required on the immediate label

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4041

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

540 ml and 1080 ml containers

[Label with no outer carton or package leaflet]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Altresyn 4 mg/ml oral solution for pigs
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

540 ml
1080 ml

5. TARGET SPECIES

Pigs (sexually mature gilts).

6. INDICATION(S)

For the synchronisation of oestrus in sexually mature gilts.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Method and route of administration

For oral use as a top-dressing.

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

Advice on correct administration

The product should be administered with the Altresyn doser only.

To prime the doser:

1. put the bottle in an 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 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 product as a top dressing to the feed. Add to the surface of the feed immediately before feeding.

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

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Meat and offal: 9 days.

9. 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.

Contraindications

Do not administer to animals suffering from uterine infection.

Do not administer to male animals.

See section "Use during pregnancy and lactation".

Adverse reactions

None known.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Special precautions for use in animals

Add the veterinary medicinal product to the feed immediately before feeding. Discard any uneaten medicated feed

Use only in sexually mature gilts who had already presented one 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.

Use during pregnancy and lactation

Do not use in pregnant or lactating animals.

Interactions, overdose, incompatibilities

None known.

10. 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.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Altresyn should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4041

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

Other information

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.

Date on which the label was last approved

{month/year}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Altresyn 4 mg/ml oral solution for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Altresyn 4 mg/ml oral solution for pigs.
Altrenogest.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

4. INDICATIONS

For the synchronisation of oestrus in sexually mature gilts.

5. CONTRAINDICATIONS

Do not administer to animals suffering from uterine infection. Do not administer to male animals.
See section "Use during pregnancy and lactation".

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sexually mature gilts).

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral use as a top-dressing.

20 mg altrenogest / animal, i.e. 5 ml per animal once a day for 18 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 product as a top dressing to the feed using the metering pump. Add to the surface of the feed immediately before feeding.

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

10. WITHDRAWAL PERIOD(S)

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.

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

12. SPECIAL WARNINGS

Do not administer to male animals.

Special precautions for use in animals

Add the veterinary medicinal product to the feed immediately before feeding. Discard any uneaten medicated feed. To use only in sexually mature gilts who had already presented one 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.

Use during pregnancy and lactation

Do not use in pregnant or lactating animals.

Interactions, overdose, incompatibilities

None known.

Other precautions regarding impact on 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Altresyn should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{month/year}

15. OTHER INFORMATION

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.

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards and to the right.

Approved 11 April 2019