PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX x 150 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Altrenogest 2.20 mg

3. PACKAGE SIZE

150 ml

4. TARGET SPECIES

Horses (mares).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 14 days.
Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

Women of child bearing age should avoid contact with the product.
This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3040

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX x 250 ml, 300 ml, 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Altrenogest 2.20 mg

3. PACKAGE SIZE

250 ml
300 ml
1000 ml

4. TARGET SPECIES

Horses (mares).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

Women of child bearing age should avoid contact with the product.
This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3040

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE x 150 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Altrenogest 2.20 mg

3. TARGET SPECIES

Horses (mares).

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 14 days.
Once opened, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE x 250 ml, 300 ml, 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Altrenogest 2.20 mg

3. TARGET SPECIES

Horses (mares).

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once opened, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Regumate Equine 2.2 mg/ml oral solution for horses

2. Composition

Each ml contains:

Active substance:

Altrenogest	2.20 mg

Excipients:

Butylhydroxyanisole (E320)	0.07 mg
Butylhydroxytoluene (E321)	0.07 mg
Sorbic acid (E200)	1.50 mg
Benzyl alcohol	10.00 mg

Clear, light yellow oily solution.

3. Target species

Horse (mares).

4. Indications for use

In mares with significant follicular activity during the transitional period between seasonal anoestrus and the breeding season (follicles of at least 20-25 mm present at the beginning of treatment):

- Suppression/prevention of oestrus (usually after 1 to 3 days of treatment) during the prolonged oestrus periods occurring during this period.
- Control of the time of initiation of oestrus (approximately 90% of mares show signs of oestrus within 5 days following the end of treatment) and synchronisation of ovulation (60% of mares ovulate between days 11 and 14 following the end of treatment).

5. Contraindications

Do not use in mares where a uterine infection has been diagnosed.
Do not use in males.

6. Special warnings

Special warnings:
In order to ensure effective use of the veterinary medicinal product, the presence of follicular activity in mares must be confirmed during the transitional period.

Special precautions for safe use in the target species:
The medicated feed should be offered to mares being treated as soon as the veterinary medicinal product has been added, and not stored.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Women who may be, or are pregnant, should not use the veterinary medicinal product.
Women of childbearing age should avoid contact with the veterinary medicinal product.
This veterinary medicinal product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

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. Transcutaneous absorption may be even higher when the area is covered by an occlusive material, such as latex or rubber gloves. Accidental spillage on the skin should be washed off immediately with soap and water.
Wash hands after treatment and before meals.
In case of incidental contact with eye, rinse thoroughly with water for 15 minutes. Get medical attention.
Effects of overexposure: repeated accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache.

Pregnancy:
Accidental administration is not detrimental as studies in mares have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Lactation:
Use during lactation is unlikely to have detrimental effects.

Interaction with other medicinal products and other forms of interaction:
Griseofulvin may alter the effects of altrenogest if administered concomitantly with this veterinary medicinal product.

Overdose:
No negative effects have been observed in horses following up to five times the recommended dose of altrenogest for 87 days and at the recommend dose for continuous periods up to 305 days.

Major incompatibilities:
None known.

7. Adverse events

Horses (mares):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Uterine infection

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

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

Oral use.
0.044 mg altrenogest (1 ml per 50 kg bodyweight) per kg bodyweight and per day, for 10 consecutive days.

9. Advice on correct administration

Carefully withdraw the volume of veterinary medicinal product corresponding to the mare bodyweight (1 ml per 50 kg bodyweight) and administer this volume via oral route.

- 150, 300 and 1000 ml bottles: Wearing gloves remove the original cap and in its place screw on the luer lock cap. Keeping the bottle upright, screw the luer lock syringe onto the cap orifice, turn the bottle upside down, and carefully withdraw the solution from the bottle using the syringe. Turn the bottle right way up before detaching the syringe. Securely replace the small cap on the luer lock cap. Replace the childproof cap on the bottle until next use.

- 250 ml bottles: Remove the white cap and the aluminium foil seal from the neck of the measuring compartment. Keeping the bottle upright, press the body of the bottle until the required volume of the veterinary medicinal product is accumulated into the measuring compartment. Carefully pour the content of the measuring compartment on the mare feed.

The veterinary medicinal product should be added to the mare's feed, at a single feeding per day, or directly administered into the mouth using a syringe.
Avoid introduction of contamination.

10. Withdrawal periods

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging:
- 150 ml bottle: 14 days.
- 250 ml, 300 ml and 1000 ml bottles: 28 days.

When the container is broached (opened) for the first time, using this in-use shelf-life, the date on which any veterinary medicinal product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as altrenogest 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 how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3040

Exists in 150 ml, 250 ml, 300 ml and 1000 ml bottles.

Not all pack sizes may be marketed.

15. 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.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue de Lyons
27460 Igoville, France

17. Other information

POM-V Veterinary medicinal product subject to prescription

Approved 25 March 2025
Gavin Hall