ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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.

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 NUMBER

Vm 06376/3040

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX x 1000 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

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.

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 NUMBER

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 1000 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 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}

B. PACKAGE LEAFLET

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

Horses (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:

Accidental exposure to this veterinary medicinal product could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache. Adverse reproductive effects reported in men include decreased libido.
Acute effects after single exposure are possible, but repeated accidental exposure has the potential for more adverse effects.

The veterinary medicinal product should not be administered by women who are or suspected to be pregnant. . 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 breast cancer or other progesterone-dependent tumours
- persons with thrombo-embolic disorders or a history of those
- persons with cerebral-vascular or coronary-artery disease
- women with vaginal bleeding of unknown cause
- persons with liver dysfunction or disease.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.
Avoid contact with the skin, eyes and oral ingestion due to hand-to-mouth contact.

Personal protective equipment consisting of overalls and chemical resistant single-use gloves (e.g. nitrile gloves) should be worn when handling the veterinary medicinal product. This veterinary medicinal product can penetrate latex or other types of porous gloves and absorption through the skin may be even higher when the area is covered by an occlusive material. Do not eat, drink or smoke while handling the product.

Wash hands after use.

In case of accidental spillage onto skin it should be washed off immediately with soap and water. Remove contaminated clothes immediately. In case of accidental contact with the eyes, rinse thoroughly with water for 15 minutes. In case of accidental ingestion do not induce vomiting as pulmonary damage via aspiration of oil base may occur. Seek medical advice immediately and show the package leaflet or the label to the physician.

Any equipment or surfaces that come into contact with the veterinary medicinal product should be adequately cleaned and decontaminated to prevent human exposure. Wear gloves when cleaning.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}
{< > to be adjusted nationally}

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 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.

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.
- 1000 ml bottle: 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 or <household waste>.
{< > to be adjusted nationally}

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> <or> <pharmacist> how to dispose of medicines no longer required.
{< > to be adjusted nationally}

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 06376/3040

Exists in 150 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 manufacturer responsible for batch release> <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

<Local representatives <and contact details to report suspected adverse reactions>:>
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
{< > to be adjusted nationally}

17. Other Information

Gavin Hall

Approved: 02 September 2026