SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Altrenogest 2.20 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole(E320)	0.07 mg
Butylhydroxytoluene (E321)	0.07 mg
Sorbic acid (E200)	1.50 mg
Benzyl alcohol	10.00 mg
Triglycerides, Medium chain	

Clear, light yellow oily solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses (mares).

3.2 Indications for use for each target species

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).

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

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. Part consumed feed must be safely destroyed and not given to any other animal.

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 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 clothing 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.
{< > to be adjusted nationally}

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Not applicable.
However, 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.

3.8 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.

3.9 Administration routes and dosage

Oral use.

0.044 mg altrenogest per kg bodyweight per day, for 10 consecutive days.

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 syringe onto the luer lock 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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03DX90

4.2 Pharmacodynamics

Altrenogest is a synthetic trienic C21 steroidal progestogen, belonging to the 19-nor-testosterone series. It is an orally active progestogen. Altrenogest decrease blood concentrations of the endogenous gonadotrophins, LH and FSH. As a consequence, it induces the regression of all large follicles
(>20-25 mm) and therefore blocks oestrus or ovulation. During the second half of the treatment period with the veterinary medicinal product, when all large follicles have regressed, there is a peak in FSH concentration which initiates a new wave of follicular growth. End of treatment is followed by a steady rise in LH concentration,

which sustains follicular growth and maturation. These endocrine effects ensure that most mares ovulate during the four day period between days 11 and 14 after the end of the treatment course.

4.3 Pharmacokinetics

Altrenogest is rapidly absorbed following oral administration and can be detected in blood as soon as 10 minutes after dosing. Maximum serum concentrations are observed 2.5 hours following administration. Altrenogest is extensively metabolised in the liver. The terminal half-life following oral administration is 10.7 hours ± 4.3 hours. Altrenogest is eliminated both via urine and faeces, in similar proportions.

Environmental properties
Altrenogest may be dangerous for fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging:

- 150 ml bottle: 14 days.
- 1000 ml bottle: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is packaged in brown opaque 150 and 1000 ml polyethylene bottles which are sealed with an induction aluminium foil seal.
The 150 ml and the 1000 ml bottles are provided with a luer lock cap which, when screwed on the bottle neck, allows the user to safely and accurately withdraw the veterinary medicinal product with a syringe that can directly adjust on the luer lock cap.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.
{< > to be adjusted nationally}

The 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/3040

8. DATE OF FIRST AUTHORISATION

05 April 2005

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2026

10. 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).

Gavin Hall

Approved: 02 September 2026