SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine 4 mg/ml oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Altrenogest 4 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylated hydroxytoluene (E321)	0.07 mg
Butylated hydroxyanisole (E320)	0.07 mg
Soybean oil, refined	

Clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sow, nullipar).

3.2 Indications for use for each target species

For the synchronisation of oestrus and improvement of litter size in sexually mature gilts.
For the synchronisation of oestrus and improvement of farrowing rate and litter size in sows.

3.3 Contraindications

Do not administer to male animals.
Do not administer to pregnant sows or those suffering from uterine infection.
Part-consumed feed must be disposed of with other waste feed and not given to other animals.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.

The veterinary medicinal product should not be handled by:

- People with known or suspected breast cancer or other progesterone-dependent tumours
- People with or thromboembolic disorders or a history of those
- People with cerebrovascular or coronary artery disease
- Women with vaginal bleeding of unknown cause
- People 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 chemically 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 on the skin, wash off immediately with soap and water. Remove contaminated clothing immediately. In case of accidental contact with 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:
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.

3.6 Adverse events

Pigs (sows and gilts):
None known.

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.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use (during the whole or part of the pregnancy).

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

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

Gilts:
One dose of 5 ml per gilt per day for 18 consecutive days given orally with feed for immediate consumption.

Sows:
One dose of 5 ml per sow per day for 3 consecutive days given orally with feed for immediate consumption.

Group feeding on the floor:
Feed should be presented in such a manner that each pig is allowed sufficient floor space to get equal access to the feed.

Once the animals have started feeding, dispense one dose of the veterinary medicinal product as a top-dressing on the feed in front of each pig.

Administration:

- Remove the cap and the obturator.
- Measure the clinical dose of 5 ml using the dosing cup provided.
- Pour the dose on the feed.
- Close the bottle with the obturator and the screwable cap after each use.

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

No special precautions required. Doses of 20 times the recommended dose did not affect pigs or their offspring.

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03DX90

4.2 Pharmacodynamics

Altrenogest has a similar action to the natural hormone progesterone. When administered orally it suppresses the normal sexual cycle, preventing signs of heat and ovulation. Withdrawal of the veterinary medicinal product then allows the natural hormones to be released again and animals return to heat in a synchronised fashion.

4.3 Pharmacokinetics

Altrenogest is rapidly absorbed following oral administration, with peak plasma concentrations being reached between 1 and 4 hours after treatment. The liver is the main organ involved in altrenogest's metabolism and biliary excretion is its main route of elimination. Following treatment, circulating altrenogest concentrations decline biphasically. Half-life of elimination was estimated to be around 14 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging (bottle): 90 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

Cardboard box containing a 540 ml or 1 000 ml aluminium bottle respectively, with a white polypropylene screw cap with tamper evident closure.
Below the cap: a polyethylene obturator with ring-pull.
A measuring cup is included.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 06376/4097

8. DATE OF FIRST AUTHORISATION

12 November 1985

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 04 June 2026