SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine, 0.4% w/v oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	**%w/v**
Altrenogest	0.4

Other ingredients

Butylated hydroxytoluene (E321)	0.007
Butylated hydroxyanisole (E320)	0.007

Each 5ml dose provides 20mg Altrenogest.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.
Clear, pale yellow, odourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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.

4.3 Contra-indications

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.

4.4 Special warning for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

Not applicable.

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

- Women who are pregnant, or suspected to be pregnant, should not use the product. Women of childbearing age should handle the product with extreme care. The 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 product. Porous gloves may let this 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 accidental contact with eye, rinse abundantly with water. 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.

(iii) 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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy or lactation

Do not administer to pregnant sows.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.9 Amounts to be administered and administration route

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

Sows: One dose of 5ml 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 Regumate as a top-dressing on the feed in front of each pig.

Administration of product supplied in 540 ml and 1L container (not pressurised):

- 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment.
Pigs may be slaughtered for human consumption only after 9 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmatherapeutic group: Sex hormones and modulators of the genital system, Progestogens, Other progestogens.

ATC Vet Code: QG03DX90

5.1 Pharmacodynamic properties

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 Regumate then allows the natural hormones to be released again and animals return to heat in a synchronised fashion.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxytoluene (E321)
Butylated hydroxyanisole (E320)
Soya oil

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the 540 ml and 1L bottle as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging of the 540 ml and 1L bottle: 90 days

Not all pack sizes may be marketed.

6.4 Special precautions for storage

540 ml and 1L bottle: do not require any special storage conditions.

6.5 Nature and composition of immediate packaging

540 ml and 1L aluminium bottle provided with an external translucent plastic dosing cup. The closure system comprises an obturator prolonged by a plastic ring inserted in the bottle neck and a screwable cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Regumate Porcine, 0.4% w/v oral solution 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.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4097

9. DATE OF FIRST AUTHORISATION

12 November 1985

10. DATE OF REVISION OF TEXT

November 2024

Gavin Hall
Approved: 22 November 2024