SPC

Regumate® Porcine

SUMMARY OF PRODUCT CHARACTERISTICS

REGUMATE® PORCINE 0.4% SOLUTION

MSD Animal Health

CONTENTS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine 0.4% solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Altrenogest 4 mg/mL

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Clear, pale-yellow, odourless oily solution

4. CLINICAL PARTICULARS

4.1 Target species

Pig

4.2 Indications for use, specifying each target species

Oestrus synchronisation in gilts allowing timed introduction of gilts in breeding batches.
Oestrus prevention / in synchronisation weaned sows.

4.3 Contraindications

None

4.4 Special warnings for each target species

None known

4.5 Special precautions for use, including special precautions to be taken by the person administering the veterinary medicinal product to animals

The duration of treatment should be carefully observed. For animals kept in group, administration of the recommended clinical dose to each animal should be ensured.
Personal protective clothing (gloves and overalls) must be worn when handling the product. Wash hands after treatment and before meals. Pregnant women and women of childbearing age should avoid contact with the product or should exercise extreme caution when handling this product. Accidental absorption could lead to disruption of the menstrual cycle or prolongation of pregnancy. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be

washed off immediately with soap and water.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Not applicable.

Lactation:
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

For oral administration
Gilts: 1 dose (5 mL) per animal/day applied on feed for 18 consecutive days.
Sows: 1 dose (5 mL) per animal/day applied on feed for 3 consecutive days.

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

None known

4.11 Withdrawal period(s)

Meat and offal: 9 days.
Animals must not be slaughtered for human consumption during treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital system.
ATCvet code: QG03DX90.
Altrenogest has an action similar to natural progesterone. During the treatment, this compound acts by negative feed back on pituitary gonadotrophins to block follicular growth and oestrus behaviour. At the end of treatment, gonadotrophin secretion resumes and promotes follicular growth and maturation. The homogeneous size of follicles at the end of treatment together with the synchronous resumption of gonadotrophin secretion in all females result in synchronized heat, 5 to 8 days follow-

ing the end of treatment.
Regumate treatment is used by pig breeders to generate homogeneous groups of animals with predictable dates of mating and/or of artificial insemination. This is helpful to include gilts in breeding batches of sows and to prevent and synchronize the first post weaning oestrus in sows.

5.2 Pharmacokinetic particulars

A peak in altrenogest concentration appears 1 hour after the first administration and around 4 hours following the 18th dose of a full treatment.
Altrenogest is rapidly absorbed by the gastro-intestinal tract.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole	0.07 mg/mL
Butylhydroxytoluene	0.07 mg/mL
Soya-bean oil	q.s. 1 mL

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf-life of the bottle as packaged for sale: 3 years
Shelf life after first opening of the immediate packaging: 90 days

6.4 Special precautions for storage

Bottle: store below 25 °C

6.5 Nature and composition of immediate packaging

The product is supplied in two container sizes:

- A 540 ml aluminium container. The closure system comprises an obturator prolonged by a plastic ring and inserted into the bottle neck and a screwable 45 mm cap. The filling volume is at least 540 mL which corresponds to the treatment of 6 gilts or 36 sows at the recommended therapeutic dose of 5 mL (dose of 20 mg of altrenogest) for 18 or 3 consecutives days, respectively.
- A 1L aluminium container. The closure system comprises an obturator prolonged by a plastic ring and inserted into the bottle neck and a screwable 45 mm cap. The filling volume is at least 1000 mL, which corresponds to the treatment of 11 gilts or 66 sows at the recommended therapeutic dose of 5 mL (dose of 20 mg of altrenogest) for 18 or 3 consecutives days, respectively.

The product is presented in a cardboard box as secondary packaging.

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

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
The Netherlands

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)

NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine 0.4% solution

COMPOSITION

Altrenogest 4 mg/mL

PHARMACEUTICAL FORM

Oily solution

PACKAGE SIZE

The product is supplied in two container sizes:

- A 540 ml aluminium container. The closure system comprises an obturator prolonged by a plastic ring and inserted into the bottle neck and a screwable 45 mm cap. The filling volume is at least 540 mL which corresponds to the treatment of 6 gilts or 36 sows at the recommended therapeutic dose of 5 mL (dose of 20 mg of altrenogest) for 18 or 3 consecutives days, respectively.
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The product is presented in a cardboard box as secondary packaging.

TARGET SPECIES

Pig

INDICATIONS

Oestrus synchronisation in gilts allowing timed introduction of gilts in breeding batches.
Oestrus prevention / in synchronisation weaned sows.

METHOD AND ROUTE OF ADMINISTRATION

For oral use.
Gilts: 1 dose (5 mL) per animal/day applied to feed for 18 consecutive days.
Sows: 1 dose (5 mL) per animal/day applied to feed for 3 consecutive days.

WITHDRAWAL PERIOD

Meat and offal: 9 days.

SPECIAL WARNINGS

Women of child bearing age should avoid contact with the product.
Personal protective clothing (gloves and overalls) must be worn when handling the product.
Wash hands after treatment and before meals.

SPECIAL STORAGE CONDITIONS

Protect from heat.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

Once opened, use by 90 days

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS (LABEL)

NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine 0.4% solution.

COMPOSITION

Altrenogest 4 mg/mL

PHARMACEUTICAL FORM

Oily solution

PACKAGE SIZE

540 ml
1 L

TARGET SPECIES

Pig

INDICATION(S)

Oestrus synchronisation in gilts allowing timed introduction of gilts in breeding batches.
Oestrus prevention / in synchronisation weaned sows.

METHOD AND ROUTE OF ADMINISTRATION

For oral use.
Gilts: 1 dose (5 mL) per animal/day applied to feed for 18 consecutive days.
Sows: 1 dose (5 mL) per animal/day applied to feed for 3 consecutive days.

WITHDRAWAL PERIOD

Meat and offal: 9 days.

SPECIAL WARNING(S), IF NECESSARY

Pregnant women and women of child bearing age should avoid contact with the product.
Personal protective clothing (gloves and overalls) must be worn when handling the product.
Wash hands after treatment and before meals.

SPECIAL STORAGE CONDITIONS

Protect from heat.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

FOR ANIMAL TREATMENT ONLY

For animal treatment only.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

BATCH NUMBER

<Batch> <Lot> <BN> <number>

EXPIRY DATE

<EXP month/year>

PACKAGE INSERT

Not applicable.
The information required is conveyed on the container or the outer package.