

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagest 4 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:

Altrenogest 4.00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxytoluene (E321)	0.07 mg
Butylhydroxyanisole (E320)	0.07 mg
Soya-bean oil refined	

A clear colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (nulliparous mature sows).

3.2 Indications for use for each target species

For the synchronisation of oestrus.

3.3 Contraindications

Do not use in boars.

Do not administer to pregnant sows (see section 3.7) or those suffering from uterine infection.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Use only in sexually mature gilts that have been in oestrus.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Discard any uneaten medicated feed.

Part-consumed feed must be safely disposed of with other waste feed and not given to any other animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product should not be administered by pregnant women or women suspected to be pregnant. Women of childbearing age should handle the product with extreme care.

The veterinary medicinal 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 equipment consisting of gloves and overalls must be worn when handling the veterinary medicinal 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. Seek 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.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

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 (nulliparous mature sows):

Undetermined frequency (cannot be estimated from the available data):	Ovarian cyst ¹
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¹Can occur in case of underdosing

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 and lactation:

Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Griseofulvin may alter the effects of altrenogest when administered concurrently with this veterinary medicinal product.

3.9 Administration routes and dosage

Oral use.

20 mg altrenogest per animal (corresponding to 5 ml of the product per animal) per day, for 18 consecutive days. Give immediately after mixing with the feed.

The volume to be administered should be measured with an appropriate dosing device.

Administration:

Animals should be segregated and dosed individually. Add the veterinary medicinal product as a top-dressing to the feed immediately before feeding.

The synchronisation of oestrus should be supervised by a veterinarian. Nulliparous mature sows should be segregated not later than 7 days before treatment. During treatment, animals should not change rooms. A complete up-take of the medicated feed should be assured.

Most treated gilts will come into oestrus 5 to 6 days after the 18th consecutive day of treatment.

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

No data available.

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

Altrenogest is a synthetic trienic C21 steroidal progestagen belonging to the 19-nor-testosterone series. It is an orally active progestagen. Altrenogest decreases 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 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.

4.3 Pharmacokinetics

Altrenogest is rapidly absorbed following oral administration. Altrenogest is extensively metabolised in the liver. Altrenogest is eliminated both via bile in faeces and via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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: 60 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

PET bottle with an unremovable plastic shell clipped or co-extruded to the bottle.
The bottle is hermetically closed with a child-proof screw cap equipped by a triseal joint.

Package size:

1 x 450 ml bottle
1 x 900 ml bottle

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.

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

Virbac S.A.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/086/001

8. DATE OF FIRST AUTHORISATION

28 May 2010

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

06 September 2024

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) (<https://medicines.health.europa.eu/veterinary>)