SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEST 4 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Altrenogest	4.00 mg/ml

Excipients:

Butylhydroxytoluene (E321)	0.07 mg/ml
Butylhydroxyanisole (E320)	0.07 mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
For top-dressing use.
A clear colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (nulliparous mature sows).

4.2 Indications for use, specifying the target species

For the synchronisation of oestrus in nulliparous mature sows.

4.3 Contraindications

Do not use in boars.
Do not administer to pregnant sows (see section 4.7) or those suffering from uterine infection.
Do not use in case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

Add the veterinary medicinal product to the feed immediately before feeding. Discard any uneaten medicated feed.

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

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

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

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

<u>Other precautions regarding impact on the environment</u>

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)

Under dosing can lead to the formation of cystic follicles.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant and lactating sows.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

For oral use as a top-dressing.
20 mg altrenogest per animal and per day, for 18 consecutive days, corresponding to 5 ml of the product per day and per animal for 18 consecutive days given orally with feed for immediate consumption.

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

Administration:
Animals should be segregated and dosed individually. Add the product as a top dressing to the feed immediately before feeding. Part-consumed feed must be disposed of with other waste feed and not given to other animals.

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 the room.
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.

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

No data available.

4.11 Withdrawal period

Meat and offal: 9 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, progestagens.
ATCvet 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 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Butylhydroxyanisole (E320)
Soya-bean oil refined

6.2 Incompatibilities

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

6.3 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.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

One PET bottle with an unremovable plastic shell clipped or co-extruded to the bottle, containing 450 ml or 900 ml of product. The bottle is hermetically closed with child proof screw cap equipped by a triseal joint.

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

The product 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

Virbac
1ère avenue - 2065m - LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/5063

9. DATE OF FIRST AUTHORISATION

28 March 2008

10. DATE OF REVISION OF THE TEXT

March 2025

Gavin Hall
Approved: 13 March 2025