PARTICULARS TO APPEAR ON THE OUTER/IMMEDIATE PACKAGE

450 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEST 4 mg/ml oral solution for pigs
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Altrenogest 4.00 mg/ml

Excipients:
Butylhydroxytoluene (E321), Butylhydroxyanisole (E320).

A clear colourless to pale yellow solution.

3. PHARMACEUTICAL FORM

Oral solution.
For top-dressing use.

4. PACKAGE SIZE

450 ml.

5. TARGET SPECIES

Pigs (nulliparous mature sows).

6. INDICATION

For the synchronisation of oestrus in nulliparous mature sows.

7. CONTRAINDICATIONS

Do not use in boars.
Do not administer to pregnant sows or those suffering from uterine infection.
Do not use in case of hypersensitivity to the active substance.
See section “Special warnings”.

8. ADVERSE REACTIONS

Under dosing can lead to the formation of cystic follicles.
If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

9. METHOD AND ROUTE OF ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Meat and offal: 9 days.

11. SPECIAL WARNING(S), IF NECESSARY

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

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.

Do not administer to pregnant and lactating sows.

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.

User warnings

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.

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

Overdose
No data available.

12. EXPIRY DATE

EXP : {month/year} Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 60 days. When the container is opened for the first time, using the in-use shelf-life which is specified on this label, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label: Once opened, use by …

13. SPECIAL STORAGE CONDITIONS

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

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

15. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

16. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of sight and reach of children.

17. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

18. MARKETING AUTHORISATION NUMBER

Vm 05653/4136

19. MANUFACTURER'S BATCH NUMBER

Batch : {number}

PARTICULARS TO APPEAR ON THE OUTER/IMMEDIATE PACKAGE

900 ml bottle

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Altrenogest

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Excipients:
Butylhydroxytoluene (E321), Butylhydroxyanisole (E320).

A clear colourless to pale yellow solution.

3. PHARMACEUTICAL FORM

Oral solution.
For top-dressing use.

4. PACKAGE SIZE

900 ml.

5. TARGET SPECIES

Pigs (nulliparous mature sows).

6. INDICATION

For the synchronisation of oestrus in nulliparous mature sows.

7. CONTRAINDICATIONS

Do not use in boars.
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Approved: 20 January 2017