

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid 20 mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Active substance(s):	mg
Megestrol acetate	20.0

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

Megestrol acetate is a potent progestagen with marked anti-oestrogenic properties. It is recommended for administration by the oral route in bitches for the postponement or prevention of oestrus and the treatment of hypersexuality which may be manifest as undesirable behaviour in male dogs.

In cats it is recommended for prevention or postponement of miliary and eosinophilic granulomata.

Postponement of oestrus (Bitches): The product may be used to postpone an anticipated oestrus. Following the recommended course it is not possible to state when the next oestrus period will occur, with any degree of accuracy, as this will depend on the stage of anoestrus when the tablets were administered. It is most likely, however, that it will appear some three months later. It is unlikely that oestrus will be delayed by more than six months.

Prevention of oestrus (suppression of heat) (Bitches): When the tablets are used by the recommended method for the prevention of oestrus, the signs of pro-oestrus usually disappear in two to three days and the subsequent oestrus normally occurs four to six weeks earlier than would have been the case had medication not been given.

Oestrus control in cats: Oestrus can be prevented or postponed by selecting an appropriate dose regime. The occurrence of the next oestrus following treatment may be variable because the cat is seasonally polyoestrus and ovulation does not occur spontaneously.

However, the next call after a prevention course given during the breeding season will probably occur a few days later than normally expected -- on average about four weeks after the last dose is given. Queens given a correctly timed postponement course will not call whilst they are receiving the tablets.

Miliary eczema in cats: Field experience has shown it to be very successful in the treatment of miliary eczema. A clinical response can be expected in most cases within the first few days of commencing treatment.

Eosinophilic granuloma (rodent ulcer) in cats: Clinical experience has shown that the product can be beneficial in this condition.

Undesirable behaviour in dogs: Trials have shown that the product is an effective treatment in 75% of dogs exhibiting the following undesirable behaviour:

Aggression -- either dominant or submissive (fear-induced)

Mounting

Territory marking by urination

Roaming

Excitability

Destructiveness

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue
2065M – LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4160

17. MANUFACTURER’S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid 20 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac S.A

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

No Approved Packaging

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Virbac
1ère avenue
2065M – LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid 20 mg Tablets

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each tablet contains:

Active substance(s):	mg
Megestrol acetate	20.0

4. INDICATION(S)

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Excitability

Destructiveness

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral Use

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[It is recommended that the following reference to the VMD Website is included:]

<Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

<15. OTHER INFORMATION>

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Vm 05653/4160

Approved: 08/09/2017

