## PARTICULARS TO APPEAR ON THE OUTER PACKAG AND THE IMMEDIATE PACKAGE {NATURE/TYPE}

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid 5 mg Tablets

#### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Megestrol acetate

#### 3. PHARMACEUTICAL FORM

Tablets.

#### 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 oestrus and the treatment of military eczema 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 with Ovarid 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 Ovarid can be beneficial in this condition.

Undesirable behaviour in dogs: Trials have shown that Ovarid 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 use

#### 8. WITHDRAWAL PERIOD

Not applicable.

#### 9. SPECIAL WARNING(S), IF NECESSARY

#### 10. EXPIRY DATE

#### 11. SPECIAL STORAGE CONDITIONS

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

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac 1 ere avenue 2065M – LID 06516 Carros France

16. MARKETING AUTHORISATION NUMBER(S)

**Vm** 05653/4161

17. MANUFACTURER'S BATCH NUMBER

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid 5 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac

- 3. EXPIRY DATE
- **4. BATCH NUMBER**
- 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

#### **PACKAGE LEAFLET FOR:**

## Ovarid 5 mg Tablets

Megestrol acetate

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

Virbac 1 ere avenue 2065M – LID 06516 Carros France

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid

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

Megestrol acetate 5 mg

#### 4. 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 oestrus and the treatment of miliary eczema 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 with Ovarid 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 Ovarid can be beneficial in this condition.

*Undesirable behaviour in dogs:* Trials have shown that Ovarid 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** 

- 5. CONTRAINDICATIONS
- 6. ADVERSE REACTIONS
- 7. TARGET SPECIES

Cats and dogs

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

Oral Use

- 9. ADVICE ON CORRECT ADMINISTRATION
- 10. WITHDRAWAL PERIOD(S)

Not applicable.

#### 11. SPECIAL STORAGE PRECAUTIONS

## 12. SPECIAL WARNING(S)

User Warnings: None.

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

#### 15. OTHER INFORMATION

POM-V

**Vm** 05653/4161

Approved: 08/09/2017