IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10988/081/002**
Case No: 7007872

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Virbac S.A.

Virbac 1, 1 ere Avenue, **2065 M - L.I.D., BP 27, 06516**, **Carros Cedex**, **France**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Ovarid Tablets 20 mg

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **19/07/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarid Tablets 20 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	mg/tablet
Megestrol Acetate	20.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Buff coloured slightly speckled biconvex uncoated tablet with a breakline on one surface

4 CLINICAL PARTICULARS

4.1 Target Species

Cats and dogs.

4.2 Indications for use, specifying the target species

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): Ovarid Tablets 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

4.3 Contraindications

Ovarid is not recommended in diabetic animals.

Male dogs intended for breeding should not be treated with Ovarid.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

It must be remembered that progestagens, like other synthetic hormones, should always be used with care. This is particularly so in bitches treated at their first oestrus. Owners should be advised that this class of bitch, and a small proportion of others which have abnormal oestrous cycles, may show excessive libido, or oestrus may return earlier than expected, because of difficulties which may be encountered with the timing of administration.

Apart from these considerations experience has shown that, when used correctly, Ovarid Tablets do not produce undesirable side-effects since oral administration allows the duration of effect to be more accurately controlled than is the case with depot injections.

In the prevention of oestrus in bitches, the timing of administration is of great importance if best results are to be obtained. If Ovarid Tablets are given once ovulation has occurred, they may aid conception.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, lethargy and increased appetite with consequent weight gain may be seen in treated animals.

As with all progestagens there is the possibility of endometrial changes. However, at the recommended doses of Ovarid there should be no adverse effects.

Very occasionally, following long term use of megestrol acetate in cats to prevent recurrence of miliary eczema, mammary hypertrophy may occur. This effect is quite distinct from mammary neoplasia and may regress on cessation of dosing. In such cases medication should be withdrawn.

4.7 Use during pregnancy, lactation or lay

Progestagens may inhibit parturition. Therefore, if Ovarid is given (to cats) during pregnancy, it should be withdrawn 2-3 weeks prior to parturition. (Ovarid is not recommended for use in pregnant bitches.)

Experience has shown that bitches conceive normally at the heat following the withdrawal of megestrol acetate. Ovarid can be given to bitches to prevent the oestrus which occurs after cessation of dosing with a postponement course.

In breeding queens it is advisable that mating should be allowed at the second or subsequent call rather than the first call after cessation of dosing.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Postponement of oestrus (Bitches): 0.5 mg/kg daily for a maximum period of forty days. The course of tablets should commence preferably fourteen but at least seven days before the effect is required. A series of postponement courses may be given provided the bitch is not medicated more than twice in any 12 month period.
The following table may be used to help in dispensing tablets:

Weight of bitch		5 mg tablets only			20 mg tablets only	
Kg	Lb	Total daily dose (mg)	No. daily	No. for maximum course (40 days)	No. daily	No. for maximum course (40 days)
Up to 5	Up to 11	2.5	½	20	---	---
6—10	12—22	5	1	40	---	---
11—15	23—33	7.5	1½	60	---	---
16—20	34—44	10	2	80	½	20
21—30	45—66	15	3	120	--	
31—40	67—88	20	4	160	1	40
41—50	89—110	25	5	200	---	
51—60	111—142	30	---	---	1½	60

Prevention of oestrus (suppression of heat) (Bitches): (a) Normal dosage regimen: 2 mg/kg daily for eight days. The course of tablets should commence at the onset of pro-oestrus as indicated by the presence of both haemorrhage and vulval swelling. The stage of the oestrus cycle may be confirmed by the examination of vaginal smears.

Weight of bitch		5 mg tablets only			20 mg tablets only	
Kg	Lb	Total daily dose (mg)	No. daily course	No. for complete course (8 days)	No. daily	No. for complete course (8 days)
2.5--5	6—11	10	2	16	½	4
6--7.5	12—17	15	3	24		
8—10	18—22	20	4	32	1	8
11—15	23—33	30	6	48	1½	12
16—20	34—44	40	---	---	2	16
21—25	45—55	50	---	---	2½	20
26—30	56—66	60	---	---	3	24
31—35	67—77	70	---	---	3½	28
36—40	78—88	80	---	---	4	32
41—50	89—110	100	---	---	5	40
51—60	111—142	120	---	---	6	48

(b) Extended dosage regimen: 2 mg/kg daily for four days followed by 0.5 mg/kg daily for 16 days.
The use of this prolonged prevention course is advised in first season bitches, and may also be beneficial in bitches with a history of false pregnancy, in some cases where other abnormalities of the oestrous cycle are known to occur and when the animal to be medicated is housed with other bitches.

Oestrus control in cats:
(i) Postponement of oestrus - 2.5 mg per cat once weekly for up to 30 weeks. Dosage should commence in anoestrus (the non-breeding season).
(ii) Prevention of oestrus -- 5 mg per cat daily for three days commencing as soon as the signs of calling are seen.

Treatment of miliary eczema (miliary dermatitis) and eosinophilic granuloma (rodent ulcer) in cats: The recommended dosage is 2.5 to 5 mg per cat every two to three days until the lesions begin to regress then once weekly until a satisfactory response is obtained. In some cases it may be necessary to give a maintenance dosage of 2.5 mg per cat weekly or fortnightly to prevent recurrence of the condition. Alternatively, repeat courses of treatment may be given as required.

Undesirable behaviour in dogs: The dosage should be adjusted according to response and the following is offered as a guide:

Initial dosing	Subsequent dosing	
	Improved -- 1 mg/kg daily for 14 days	
2 mg/kg daily for 7 days		Improved -- 1 mg/kg daily for 14 days
	Not improved -- 4 mg/kg daily for 7 days	
		Not improved -- cease treatment

In a minority of animals, it may be necessary to prescribe a low maintenance dose on a once weekly basis or to give repeat short courses of medication as required.
Treatment with Ovarid in conjunction with re-training appears to increase the level of success in cases of undesirable behaviour.

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

The effects of overdose of Ovarid have not been investigated, however effects consistent with its progestational activity could be expected.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Progestogens

ATCvet Code: QG03AC05

5.1 Pharmacodynamic properties

Megestrol acetate is an established pharmacopoeial progestagen which is of greater potency than progesterone both as a progestational agent and as an inhibitor of ovulation. 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 and eosinophilic granulomata.

5.2 Pharmacokinetic properties

Absorption of megestrol acetate from the gastro-intestinal tract is variable following oral administration; peak drug concentrations in plasma occur 1 to 3 hours after a dose by mouth. It is excreted in urine, mainly as unchanged drug; metabolites account for only about 5 to 8% of the dose administered.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Phosphate
Maize Starch
Dried Yeast

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

Aluminium foil / polyethylene strips.
Packaged in cartons of: 200 x 20 mg tablets.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

VIRBAC SA,
1 ère avenue,
2065M, LID,
F-06516 Carros,
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/081/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

19th July 2010