IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10988/046/002
Case No: 7002247

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Virbac Laboratories

1 ere Avenue - 2065 m, **L.I.D.**, **06516 Carros Cedex**, **France**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Contralac 2mg Tablet

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Contralac 2 mg Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance:

Metergoline 2 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Circular, cream coloured tablet

4 CLINICAL PARTICULARS

4.1 Target Species

Female dogs.

4.2 Indications for use, specifying the target species

For the interruption of pseudo-pregnancy lactation and the interruption of post-partum lactation.

4.3 Contraindications

Do not use in pregnant animals.
Do not use in case of known 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

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Sometimes vomiting may be observed at beginning of treatment.
Slight diarrhoea may occur.
There may also be behaviour changes (agitation).

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration.
Bitch: 0.2 mg/kg of metergoline per day in 2 doses, i.e. 1 tablet morning and night per 20 kg bodyweight.
Treatment should be carried out for 4 days.
In case of persistence of symptoms after treatment, treat for another 4 days (i.e. a total of 8 days).

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

None.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Metergoline exhibits anti-prolactin action. This inhibition of secretion of prolactin, the milk-producing hormone, results in a few days in a regression of symptoms commonly encountered during pseudo-pregnancy or unwanted post-partum lactation: behaviour changes, swelling of the mammae, production of serous fluid, or even milk by the mammae.
Metergoline, unlike other anti-prolactin compounds, does not exert an anti-dopaminergic action at the recommended dosage, which reduces vomiting.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Starch Glycollate
Povidone K30
Potato Starch
Magnesium Stearate
Lactose

6.2 Incompatibilities

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

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

Blister aluminium – plastic of 8 tablets.
Box of 1, 2 or 20 blisters.

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 Laboratories
1 ère Avenue 2065 m LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/46/2

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th December 2002