IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10996/076/001**
Case No: 7006440

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:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **Ireland**

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:

Mesalin Solution for Injection, 0.2mg/ml

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **20/01/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Mesalin Solution for Injection, 0.2mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of product contains:

Active Substance		
Estradiol benzoate	0.2	mg
Excipient		
Arachis oil to	1	ml

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to pale yellow, sterile, oily, non-aqueous solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs (bitches).

4.2 Indications for use, specifying the target species

Mesalin is indicated solely for the prevention of pregnancy following mis-mating (mesalliance) in the bitch.

4.3 Contraindications

Mesalin should not be administered to cats.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

None

4.6 Adverse reactions (frequency and seriousness)

Large doses of oestrogens have been associated in the dog with blood dyscrasias and pathological changes in the uterus. Mesalin has been formulated to facilitate the administration of a low but effective dose of oestradiol benzoate to help to minimise the occurrence of side effects.

Because the amount of oestrogen given to the bitches is low when Mesalin is used, prolonged oestrus with the risk of further, possibly fertile, matings is largely avoided. False pregnancies, pyometra and vaginal discharges are commonly seen after oestrus in normally cycling unmated bitches and may occur with similar frequency following the administration of Mesalin.

In trial work, pregnancy was found to continue in up to 5% of bitches despite Mesalin treatment. It is suggested that owners are advised accordingly before the treatment is commenced.

4.7 Use during pregnancy, lactation or lay

Intended to prevent pregnancy after mesalliance.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Dosage: 0.01mg/kg (0.5ml/10kg) to be given on the 3rd and 5th day after mating.

A third dose may be administered 7 days after mating if circumstances dictate e.g. if the bitch has been observed to have been mated several times or where the timing of the unwanted mating is unknown.
Administer by subcutaneous or intramuscular injection. The product does not contain an antimicrobial preservative. Swab the septum prior to removal of each dose. Use a dry sterile needle and syringe.

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

No special treatment or antidote recommended.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

In the female, oestrogens are responsible for initiating oestrus and the changes in the reproductive system in preparation for impregnation and fertilisation, prior to the further developments promoted by progesterone.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life is 5 years. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.4 Special precautions for storage

Do not store above 25^{o}C. Protect from light. At a low temperature, the product may become viscous. Warming the vial in the hand will return the contents to the normal state.

6.5 Nature and composition of immediate packaging

Clear, Type I (Ph. Eur.) glass vials containing with halogenated butyl rubber stoppers and aluminium crimp caps. Contents 5 ml.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/076/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th January 2010

10 DATE OF REVISION OF THE TEXT