IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/153/001**
Case No: 7007547

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:

Prevac Pro

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 revoked, shall continue in force from **08/04/2010**.

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

Equilis Pro
Prevac Pro (IE and UK)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition
Equilis Pro is an inactivated vaccine containing antigen components of the equine influenza strains A/equi 1/Prague/1/56 (H7N7), A/equi 2/Newmarket/1/93 (H3N8, American-type) and A/equi 2/Newmarket/2/93 (H3N8, European-type). Aluminium hydroxide is added as an adjuvant. Sodium timerfonate is added as a preservative.

Active Substances:	per dose (2 ml)
Inactivated Influenza virus antigen of the strains:	
A/equi 1/Prague 56	50 µg HA *
A/equi 2/Newmarket 1/93	20 µg HA
A/equi 2/Newmarket 2/93	20 µg HA

* Haemagglutinin, measured by SRD

Excipients	
Aluminium hydroxide	9 mg
Sodium timerfonate (as preservative)	0.02 mg
Formaldehyde	≤ 0.4 mg

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and ponies from 4 months of age

4.2 Indications for use, specifying the target species

Active immunisation of horses and ponies to reduce infection and clinical signs caused by equine influenza virus. Onset of immunity is at 2 weeks after the second vaccination. Duration of immunity is at least one year after the third vaccination.
Active immunisation of pregnant mares in order to provide passive immunity to the progeny against equine influenza. Booster vaccination of pregnant animals may result in passive immunity in their offspring lasting for about 4-6 months.

4.3 Contraindications

Do not use in sick animals or in animals that have intercurrent disease, heavy parasitic infestation or are in poor general condition, since in these cases no satisfactory immune response can be expected.

4.4 Special warnings for each target species

Only vaccinate healthy animals.
In any group of animals a small number of individuals may fail to respond to vaccination as a result of immunological incompetence or for some other reasons.

4.5 Special precautions for use

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, wash the area with water, seek medical advice and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Adverse reactions are rare. A transient swelling at the injection site up to 3 cm in diameter, lasting for 2 to 3 days, may occur. A slight increase in body temperature, up to 1.5°C, may be observed the day following vaccination.

Occasional hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or lay

The vaccine can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other, except Equilis Tetanus Vaccine (UK, IE: Tetanus Toxoid Concentrated). It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Deep intramuscular injection of 2 ml into the neck or into the chest area.
The vaccine vial or syringe should be shaken well before use.

Basic immunisation:
All horses not previously vaccinated should be vaccinated twice with 4-6 weeks interval, followed by a third vaccination 5-7 months later.

Foals should ideally be vaccinated at about 6 months of age. If vaccination is intended before this age, animals should be tested for the absence of maternally derived antibodies, but foals should be at least 4 months of age before vaccination.

Revaccination:
Every 12 months.

Active immunisation of animals during pregnancy
A booster vaccination of pregnant mares 4-8 weeks prior to foaling leads, via the colostrum, to passive immunisation of the foals for their first 4-6 months of life.
Particularly when vaccinating pregnant animals, stress should be avoided.

Foals from fully vaccinated mares should take up colostrum within the first 24 hours of life.

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

The vaccine has been shown to be safe when administered at twice the recommended dose. Other effects than those described in section 4.6 are not to be expected.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against equine influenza
To stimulate active immunity in order to provide passive immunity to the progeny against equine influenza
ATC vet code: QI05AA01

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

Three years. Broached vials should be used within 8 hours (1 working day).

6.4 Special precautions for storage

Store at 2 - 8°C (in a refrigerator). Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

Injection vials:
2 ml (single dose presentation) or 10 ml (5 dose presentation) injection vial of glass type I (Ph. Eur.) closed with injection stoppers of chlorobutyl rubber type I (Ph. Eur.) and sealed with an aluminium crimp cap.

Pre-filled syringes:
2 ml (single dose presentation) pre-filled syringe of glass type I (Ph. Eur.) closed with a chlorobutyl-covered piston and a stopper of chlorobutyl rubber type I (Ph. Eur.).

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

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

8 MARKETING AUTHORISATION NUMBER(S)

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