

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/158/002**

Case No: 7007677

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:

Equilis Resequin Suspension for injection, for horses

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 **25/01/2010**.

Signed on behalf of the Irish Medicines Board

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

Equilis Resequin Suspension for injection, for horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Per dose (2 ml)

Inactivated equine herpes virus type 1 (EHV1), strain RAC-H at least $10^{7.8}$ TCID₅₀ *

Inactivated equine herpes virus type 4 (EHV4), strain 2252 at least $10^{6.5}$ TCID₅₀ *

Inactivated equine influenza virus-antigens of the strains

A/equi 1/Prague/1/56 50 microgram HA **

A/equi 2/Newmarket/1/93 (American type) 20 microgram HA

A/equi 2/Newmarket/2/93 (European type) 20 microgram HA

Adjuvants:

Aluminium hydroxide 15 mg

Immunostim ¹⁾ 40 microlitre

1) Consisting of emulsified cell wall extract of *Mycobacterium phleil*.

Excipient:

Sodium timerfonate 50 microgram

For a full list of excipients, see section 6.1.

* Tissue culture infective dose 50%; Antigen concentration that induces antibody levels in mice of $\geq 1:16$ for EHV1 and $\geq 1:80$ for EHV4

** Haemagglutinin; Antigen concentration that induces antibody levels in guinea pigs not significantly lower than reference preparation

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

For active immunisation of horses and ponies for reduction of respiratory disease caused by equine herpesvirus type 1 (EHV 1), equine herpesvirus type 4 (EHV 4) and equine influenza viruses (EIV) of A/equi 1 and the current “American” and “European” strains of A/equi 2.

Specific claims

EHV 1:

In the presence of field infections the vaccine induces complement fixing (CF) and virus neutralising (VN) antibody titres leading to a significant reduction of the duration of virus excretion and a notable reduction of the virus re-isolation rate compared to unvaccinated controls as demonstrated in a challenge trial.

EHV 4:

In the presence of field infections the vaccine induces complement fixing (CF) and virus neutralising (VN) antibody titres leading to a notable reduction of clinical signs (i.e. pyrexia and nasal discharge) and of challenge virus excretion in the vaccinates compared to the unvaccinated controls.

In the presence of field infections immunity against EHV-1 and EHV-4 is established within two weeks after the basic vaccination. Data from challenge experiments one month after primary vaccination show protective immunity. Revaccination at 6 months interval maintains the active immunity.

EIV:

The vaccine induces haemagglutination-inhibiting (HI) and single radial haemolysis (SRH) antibody levels against equine influenza strains of A/equi-1/Prague 1/56 (H7N7) and of the current ‘European’ and ‘American’ variants of the A/equi-2/Newmarket 2/93 and Newmarket 1/93 (H3N8) subtypes.

This results in a significant reduction of the level and duration of virus excretion and a significant reduction of clinical signs (pyrexia, coughing, nasal discharge) upon infection with equine influenza virus.

Within two weeks after the basic vaccination protective immunity against EIV is obtained. Revaccination at 6 months interval maintains the active immunity.

4.3 Contraindications

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

4.4 Special warnings for each target species

All the horses in a herd should be vaccinated (herd immunity), to reduce pressure of infection within the population. At least the first two vaccinations of the basic vaccination scheme should have been given to any new horse before placing in a stable, before any change of stable, and before attending at tournaments or races.

To optimise protection that is induced by the vaccine against EHV and EIV the following requirements must be met:

- Regular vaccinations of the entire herd.
- Avoid transfer of unimmunised or sick horses into correctly immunised herds.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Equilis Resequin is an adjuvanted vaccine and immunisation may occasionally result in temporary swellings at the injection site. Flat swellings up to 7 cm may occur. Only very rarely larger swellings can be seen. Typically, these swellings do not cause any trouble and disappear within one week, maximally within two weeks. Rise in body temperature of up to 1.5 °C may occasionally occur on the day after vaccination.

Occasional hypersensitivity reactions caused by egg-derived constituents in the vaccine 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 of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

For horses: deep intramuscular injection of 2 ml into the neck or into the chest area.

Basic immunisation:

All horses not previously vaccinated should be vaccinated twice with about 6 weeks (V1-V2) interval, followed by a third vaccination two to six months later (V3).

Foals should ideally be vaccinated at about six 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 6 months.

The vaccine syringe should be shaken well before use.

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

Following the administration of a double dose of vaccine, no side-effects other than those described under 4.6 have been observed.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated viral vaccine. ATC vet code: QI05AA04.

The vaccine is intended to stimulate active immunity in horses against equine herpesvirus type 1, equine herpesvirus type 4 and equine influenza virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium timerfonate, PBS, formaldehyde

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the container: 8 hours.

6.4 Special precautions for storage

Store in a refrigerator (2° C - 8° C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

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)

VPA 10996/158/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th January 2010

10 DATE OF REVISION OF THE TEXT