IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/145/001**
Case No: 7005485

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:

Heptavac

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 **30/01/2009**.

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

HEPTAVAC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:		per dose (2ml)
Cl.perfringens type B beta toxoid	60 - 120	TCP units
Cl.perfringens type C beta toxoid	60 - 120	TCP units
Cl.perfringens type D epsilon toxoid	160 - 320	TCP units
Cl.septicum toxoid	6 - 12	TCP units
Cl.tetani toxoid	12 - 24	TCP units
Cl.novyi toxoid	16 - 32	TCP units
Cl. chauvoei: formalin killed cells and equivalent toxoid of strains 655,656,657,658, 1048	2.50×10^8 cells	+ equivalent toxoid per strain.
Adjuvant		
Aluminium hydroxide	750	mg
Excipients		
Preservative		
Thiomersal	0.26	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and pregnant sows.

4.2 Indications for use, specifying the target species

Sheep: For the active immunisation of sheep to reduce mortality and clinical signs of lamb dysentery, pulpy kidney, struck, tetanus, braxy, blackleg and black disease, caused by *Clostridium perfringens* types B, C and D, *Cl.septicum*, *Cl.novyi*, *Cl.chauvoei* and *Cl.tetani.*

The vaccine may be used in pregnant ewes to provide passive immunisation of their lambs to reduce mortality and clinical signs of lamb dysentery, pulpy kidney and tetanus provided that the lambs receive sufficient colostrum during the first 1-2 days of life.

Passive protection against clostridial disease will persist for approximately 3 weeks.

Pregnant sows: For the active immunisation of pregnant sows to reduce mortality and clinical signs against diseases caused by *Clostridium Perfringens* type C and *Clostridium tetani*. Sows have also been shown to seroconvert to *Clostridium novyi* and field data indicate protection.

The vaccine may be used in pregnant sows to provide passive immunisation of their piglets to reduce mortality and clinical signs of diseases caused by *Clostridium tetani* for at least 14 days and against *Clostridium Perfringens* type C for a shorter period, provided that the piglets receive sufficient colostrum during the first 1 – 2 days of life.

For both sheep and pregnant sows, significant levels of immunity cannot be expected until two weeks after the second dose of the primary vaccination course.
Active immunity to the clostridial diseases is expected to persist for up to one year.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Heptavac should not be used in lambs less than 3 weeks of age due to the possible immunological incompetence of the very young lamb and competition from any maternally derived colostral antibodies.

Do not vaccinate unhealthy animals.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

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

4.6 Adverse reactions (frequency and seriousness)

Immunisation may result in temporary swellings at the injection site lasting for up to 3-4 months after vaccination. Typically, these swellings may be warm when compared to the surrounding area for up to 14 days after vaccination. Safety studies in lambs have shown that the swellings did not appear to inconvenience the animals or hinder neck movement.
Minor temperature increases (approximately 1°C – 2°C) lasting for up to 1 week may occur following vaccination of lambs.
Occasional hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

When vaccinating pregnant animals, stress should be avoided during the later stages of pregnancy.

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. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Administration is by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions. Shake bottle well before use.

Sheep:

Basic vaccination scheme
Breeding sheep:
All sheep must receive two injections, each of 2.0 ml, separated by an interval of 4-6 weeks. In adult breeding ewes, the second 2 ml dose must be administered 4-6 weeks prior to lambing.
Lambs:
Lambs being retained for fattening or subsequent breeding will require a full course of vaccination. At a minimum age of 3 weeks these lambs should receive two injections, each of 2.0ml, seperated by an interval of 4 - 6 weeks.

Re-vaccination scheme:
A 2ml booster injection at intervals of not more than 12 months. In adult breeding ewes these yearly booster injections should be given 4 - 6 weeks prior to lambing to allow passive protection of lambs via colostrum.

Sows:

Basic vaccination scheme:
Two injections of 5ml each with an interval of at least 3 weeks, the second dose to be administered at least 3 weeks before farrowing. The preferred schedule is injection at 6 and 3 weeks prior to expected farrowing date.
Re-vaccination scheme:
A single 5ml booster dose in subsequent pregnancies at not less then 3 weeks before farrowing.

Syringes and needles should be from gamma-irradiated packs or freshly sterilised by boiling for at least 20 minutes. No alcohol or disinfectants should be used for this sterilisation procedure.

The use of an automatic vaccinator is recommended. Since the bottle is non-collapsible, a vaccinator with a vented draw-off spike or similar device must be used. The instructions supplied with such syringes should be noted and care taken to ensure the delivery of the full dose, particularly with the final few doses from the bottle.

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

Accidental overdosage is unlikely to cause any reactions other than those described in point 4.6.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code; QI04AB01:Pharmacotherapeutic Group; immunologicals for ovidae, clostridium.

ATC Vet Code; QI09AB12:Pharmacotherapeutic Group; immunologicals for porcine, clostridium.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Trometamol
Maleic acid
Sodium chloride
Thiomersal
Formaldehyde
Purified Water

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 10 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

Carton with one LDPE bottle containing of 50 ml, 100 ml, 250 ml and 500 ml volume. The bottles are closed with a rubber disc (Intervet UK Ltd) or rubber stopper (Laboratorios Intervet, Salamanca) with aluminium overseal combination cap. Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/145/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th August 2008

10 DATE OF REVISION OF THE TEXT

30th January 2009