IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10007/037/001**
Case No: 7006775

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:

Boehringer Ingelheim Ltd

Ellesfield Avenue, **Bracknell**, **Berkshire RG12 8YS**, **England**

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:

Ingelvac PRRS KV emulsion for injection for pigs (sows and gilts).

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **11/05/2010**.

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

Ingelvac PRRS KV emulsion for injection for pigs (sows and gilts).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Inactivated Porcine Reproductive and Respiratory Syndrome (PRRS) virus, P120 strain: ≥ 2.5 log10 IF* Units.

*IF Units: ImmunoFluorescence antibody titre obtained after two injections in pigs under specific laboratory conditions.

Adjuvant:
O/w oily excipient (containing hydrogenated polyisobutene as adjuvant): q.s. 1 dose of 2 ml.

Excipients:

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (sows and gilts).

4.2 Indications for use, specifying the target species

Reduction of the reproductive disorders caused by Porcine Reproductive and Respiratory Syndrome virus (European strain) in a contaminated environment: vaccination reduces the number of early farrowings and the number of still-births.

4.3 Contraindications

None.

4.4 Special warnings for each target species

In PRRS infected herds, viral infection is heterogeneous and varies over time. In such context, the implementation of a vaccination program is a tool to improve the reproductive parameters and may contribute to the disease control in conjunction with sanitary measures.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.
Apply usual procedures for the handling of animals

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

To the user :
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may induce a transient oedema (at most 3 cm) lasting generally less than one week and small local reaction (granulomas), without any effect on the health and the reproductive performance of the animal. Larger reactions (up to 7 cm diameter) have been observed occasionally after frequently repeated revaccinations. Vaccination may rarely cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment should be carried out.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Data are available which demonstrate that this vaccine can be administrated on a same day in a separate site, with inactivated vaccines against parvovirosis, influenza and Aujeszky’s disease as no adverse effect on the serological response has been observed.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

Apply usual aseptic procedures.
One dose of 2 ml is administered by deep intramuscular route, in the neck muscles behind the ear, according to the following vaccination scheme:

Primary vaccination:

Gilts:
2 injections 3-4 weeks apart, at least 3 weeks before mating.

Sows:
2 injections 3-4 weeks apart (vaccination of all the sows of the herd within a short period is recommended).

Revaccination:
One injection at 60-70 days of each gestation, as of the first gestation following the primary vaccination.

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

After the administration of a double dose, no adverse reactions other than those described in section 4.6 were observed.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code : QI09AA05

The vaccine contains inactivated PRRS virus in an oily adjuvant. It is intended to stimulate immunity against PRRS virus. The efficacy was demonstrated under field conditions during field trials. Whereas no effector immunomechanism on protection has been shown, the uptake of the vaccine has been demonstrated by the production of specific anti-PRRS IFA antibodies in vaccinated animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated polyisobutene
Polyoxyethylene fatty acids
Ether of fatty alcohols and of polyols
Benzyl alcohol
Triethanolamine
Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride
Calcium chloride
Water for injections

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: 18 months.
Shelf-life after first opening the vial: Use immediately after opening.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:
- Type I glass bottle
- Nitril elastomer closure
- Aluminium cap

Packaging intended for sale:
- Box of 1 bottle of 5 doses
- Box of 10 bottles of 5 doses
- Box of 1 bottle of 10 doses
- Box of 10 bottles of 10 doses
- Box of 1 bottle of 25 doses
- Box of 10 bottles of 25 doses

Not all pack sizes may be marketed.

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

Boehringer Ingelheim Ltd.,
Ellesfield Avenue,
Bracknell,
Berks.
RG12 8YS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/037/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th May 2010

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Ingelvac PRRS KV Emulsion for injection for pigs (sows and gilts) is restricted or prohibited in Ireland pursuant to national animal health policy.

Any person intending to import, sell supply and/or use Ingelvac PRRS KV Emulsion for injection for pigs (sows and gilts) must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.