

**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA: **10996/184/001**

Case No: 7000605

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) 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:

**Bovilis Ringvac**

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 **17/07/2006**.

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

Bovilis Ringvac, lyophilisate for suspension for injection, for cattle

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 ml of vaccine:

**Active substance:**

Attenuated *Trichophyton verrucosum*, strain LTF-130  $\geq 9 \times 10^6$  and  $\leq 21 \times 10^6$  viable microconidia.

**Excipients:**

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Cattle.

##### 4.2 Indications for use, specifying the target species

Active immunisation of calves and cattle at risk of infection, or calves and cattle suffering from dermatophytosis induced by *Trichophyton verrucosum*. The prophylactic vaccination reduces clinical signs of *Trichophyton verrucosum* induced dermatophytosis while the therapeutic use results in a 2-fold faster recovery of animals which already show clinical signs of disease.

Protective immunity is present within 3 weeks after vaccination and was shown to last for at least one year in a laboratory study. Field experience shows that if consequent herd immunisation is practised generally no revaccinations are required (cf. section 4.9).

##### 4.3 Contraindications

Animals with fever and / or with dermatophytosis -independent symptoms of an infectious disease, as well as animals that are treated with corticosteroids, must be excluded from vaccination.

##### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

### Special precautions for use in animals

None.

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

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

## 4.6 Adverse reactions (frequency and seriousness)

In very rare cases a hypersensitivity reaction e.g. anaphylactic reaction may occur after vaccination. Three to eight days after vaccination a local reaction characterised by local swellings, hairless places or very small crusts – up to 2 centimeter diameter - , which decrease slowly after 3 weeks over a period up to 3 months, might occur at the injection site. No subcutaneous or intramuscular tissue changes have been observed at the injection site. Mainly after therapeutic use an increase of the body temperature up to 2.5 °C may be observed for up to two days. Animals which are in the incubation phase at the time of vaccination may develop the disease in spite of vaccination. However, the skin changes heal within approx. four weeks after the second injection.

## 4.7 Use during pregnancy, lactation or lay

Dams can be vaccinated with both the prophylactic and therapeutic dose during each stage 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. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

## 4.9 Amounts to be administered and administration route

### Administration:

Intramuscular injection, preferably in the side of the neck, with an interval of 10 - 14 days. Successive injections should be administered at alternative sides of the body.

### Dosage:     Prophylactic vaccination

Calves up to four months: 2 ml  
Animals over 4 months: 4 ml

### Therapeutic use

Calves up to four months: 5 ml  
Animals over 4 months: 10 ml

### Basic vaccination

The entire herd should be vaccinated twice with an interval of 10 - 14 days.

### Further vaccinations

After the whole herd is vaccinated, only newly born calves or additionally purchased animals are vaccinated twice with an interval of 10 - 14 days. No revaccination is necessary if all the animals of the herd are vaccinated.

Vaccinated animals should not be housed among non-vaccinated animals showing clinical signs of *Trichophyton verrucosum* infection before having reached full immunity. Animals introduced into a vaccinated herd should either be free of dermatophytosis or be vaccinated therapeutically and kept separate until they are fully recovered from disease.

### Preparation of the vaccine:

Before application, resuspend the lyophilisate with the solvent. Shake well to achieve complete suspension. Do not use after the expiration date.

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

No other effects than those described at section 4.6 are to be expected.

#### **4.11 Withdrawal Period(s)**

Zero days.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

To stimulate active immunity against dermatophytosis caused by *Trichophyton verrucosum*.

ATC vet code: QI02AP01

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

##### Lyophilisate

Gelatin, sucrose.

##### Solvent

Sodium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, water for injections.

#### **6.2 Incompatibilities**

Do not mix with any other vaccine or immunological product.

#### **6.3 Shelf-life**

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

Shelf-life after reconstitution according to directions: 6 hours

#### **6.4 Special precautions for storage**

Store the lyophilisate in a refrigerator (2 °C – 8 °C).

Protect from light.

#### **6.5 Nature and composition of immediate packaging**

Cardboard box with 1 glass vial of lyophilisate with rubber stopper and aluminium cap and 1 glass vial of solvent of 10 or 40 ml with rubber stopper and aluminium cap.

Not all pack sizes may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

**7 MARKETING AUTHORISATION HOLDER**

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

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10996/184/1

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

17th July 2006

**10 DATE OF REVISION OF THE TEXT**

None