

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10974/014/001

Case No: 7002616

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Novartis Animal Vaccines Ltd

4 Warner Drive, Springwood Industrial Estate, Rayne Road, Braintree, Essex CM7 2YW, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Torvac

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **20/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TORVAC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substance(s):</u>	per 2 ml dose
Respiratory syncytial virus (RSV) (inactivated)	2 x 10 ⁵ SW129 NM7 cells expressing RSV antigen
<u>Excipients</u>	
<i>Adjuvant</i>	
Quil A	1.0 mg
<i>Preservative</i>	
Thiomersal Ph. Eur.	0.013% w/v

3 PHARMACEUTICAL FORM

Suspension for injection.

Torvac is presented as a transparent aqueous liquid containing a cell suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

The product is indicated for use in cattle, particularly young calves from 10 days of age.

4.2 Indications for use, specifying the target species

Torvac is indicated for the active immunisation of calves thereby delaying the onset and reducing the duration of viral shedding due to Bovine Respiratory Syncytial Virus. Calves have been shown to be protected from 21 days after second vaccination and the serological response to vaccination persists for at least 12 months post initial vaccination.

4.3 Contraindications

Do not administer to animals that have previously shown a hypersensitivity reaction. Avoid vaccination of animals that have intercurrent disease, are on a course of concomitant therapy or have a poor nutritional status.

4.4 Special warnings for each target species

A small number of individuals may fail to respond to vaccination as a result of immunological incompetence or for some other reason. Satisfactory immune responses will only be attained in healthy animals.

The presence of maternal antibody may reduce the serological response to vaccination and may reduce the level of efficacy achieved with this product.

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

Care should be taken to avoid accidental self-injection. Accidental self-injection may cause an inflammatory response and medical advice should be sought in these cases.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur.
Should anaphylaxis occur, use epinephrine (adrenaline).

Transient pyrexia and injection site inflammatory reactions are likely in the majority of treated animals. The pyrexia may last for up to 72 hours. The local reaction consists of a diffuse subcutaneous oedema of approximately 40 mm diameter that normally resolves within 2-3 weeks of vaccination.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating animals.

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.

4.9 Amounts to be administered and administration route

Shake the container well before withdrawing doses.
Take adequate precautions to maintain sterility.
Administer the vaccine using an aseptic technique.
The dose is 2 ml administered by subcutaneous injection. The following vaccination programme is recommended:

Calves under 9 weeks of age
3 x 2 ml doses at 21 day intervals

Calves 9 weeks of age or over
2 x 2 ml doses at a 21 day interval

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

The administration of an overdose via the subcutaneous route will result in marked swelling at the injection site and a transient pyrexia. The swelling will resolve over the following two to three weeks without permanent sequelae and the pyrexia will resolve within 72 hours. No specific treatment is necessary.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Classification: QI02AA02

Torvac is used to induce an active immunity in cattle against Bovine Respiratory Syncytial Virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quil A 'Declared in product literature'
Thiomersal 'Declared in product literature'
Phosphate Buffered Saline

6.2 Incompatibilities

Do not mix with any other immunological product.

6.3 Shelf-life

28 months.

Shelf-life of broached vial

Once broached, use immediately.

6.4 Special precautions for storage

Store at between +2°C to +8°C.

Do not freeze. Protect from light.

Avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator.

6.5 Nature and composition of immediate packaging

Container: 20 ml Type 1 glass vial

Closure: Bromobutyl bung with aluminium overseal

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Novartis Animal Vaccines Ltd.,
4, Warner Drive,
Springwood Industrial Estate,
Rayne Road,
BRAINTREE CM7 2YW,
Essex,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10974/14/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th July 2006

10 DATE OF REVISION OF THE TEXT

None