

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tracherine

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each dose of Tracherine contains the following:

#### **Active substances:**

Live attenuated virus of Infectious Bovine Rhinotracheitis (IBR) strain ts RLB 106:

minimum:  $10^{5.5}$  CCID<sub>50</sub> per dose

For full list of excipients, see Section 6.1

### **3. PHARMACEUTICAL FORM**

Lyophilised nasal powder with sterile diluent for reconstitution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Calves and growing cattle.

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

For active immunisation of calves to reduce viral shedding and clinical signs caused by Infectious Bovine Rhinotracheitis virus (Bovine Herpesvirus type 1).

Onset of immunity occurs by 4 days after vaccination.

Duration of protection has been demonstrated for up to 6 months after vaccination.

#### **4.3 Contraindications**

Do not vaccinate unhealthy animals.

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

Do not vaccinate animals for at least one month after cessation of corticosteroid treatment.

If an anaphylactic response occurs, institute appropriate antihistaminic therapy.

The vaccine viruses may spread to susceptible contact animals, which may cause these animals to seroconvert to IBR virus. It is therefore recommended to vaccinate all animals housed together at the same time.

#### **4.5 Special precautions for use**

- i) Special precautions for use in animals

None.

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

No special precautions are needed for other livestock, vaccinators or stock handlers.

#### **4.6 Adverse reactions (frequency and seriousness)**

Vaccination may be followed by pyrexia, which may last from 1 to 4 days and will usually resolve without medication.

#### **4.7 Use during pregnancy, lactation or lay**

Can be used during 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 except Rispoval™ RS. 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**

##### *Dosage and route of administration:*

Reconstitute the entire constituents of the vaccine vial with the whole sterile diluent using the needle and the syringe provided. For each animal, withdraw 2 ml of reconstituted vaccine, substitute nasal applicator for the needle and instil 2 ml into one nostril, holding head up gently but firmly. One applicator is supplied for every dose.

Take care to avoid the introduction of contamination while reconstituting and withdrawing vaccine.

The vaccine should be used immediately after reconstitution and not stored.

*Vaccination programme:*

*Animals older than 10 weeks of age*

A single dose of vaccine should be administered.

*Animals from 3 weeks to 10 weeks of age*

Since maternal antibodies may interfere with the development of immunity in very young calves it is advisable to give two doses of vaccine, at least 14 days apart. The first dose may be given at any time from 3 weeks of age. The second dose should not be given until at least 10 weeks of age.

*Revaccination*

In order to maintain immunity, animals should be revaccinated every 6 months with a single dose of vaccine.

Alternatively, in areas where IBR is enzootic, revaccination can be given before outbreaks are expected. In particular bought in heifers or dairy replacements returning to the herd after being reared elsewhere should be vaccinated before joining adult cows.

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

No post vaccination reactions other than the ones quoted above under point 4.6 have been observed with ten times overdose of Tracherine.

**4.11 Withdrawal period(s)**

Zero days.

**5. IMMUNOLOGICAL PROPERTIES**

To stimulate active immunity against Infectious Bovine Rhinotracheitis virus (bovine herpes virus-1).

ATC VET CODE: QI02AD01

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Neomycin  
Gentamycin

**6.2 Incompatibilities**

Do not mix with any other veterinary medicinal product except the diluent supplied.

**6.3 Shelf life**

2 years.  
Reconstituted vaccine should be used immediately.

**6.4 Special precautions for storage**

Store and transport between +2°C and +8°C away from light. Do not freeze.

**6.5 Nature and composition of immediate packaging**

Cardboard carton containing a 5 dose type I glass vial closed with a rubber stopper and sealed with an aluminium cap and a type I hydrolytic glass vial containing 10 ml of diluent. Also supplied in a carton containing 20 x 5 dose vials, supplied together with a carton containing 20 x 10ml vials of diluent. Needles and syringes for reconstitution and nasal applicators for vaccination are provided in separate accessory packs.

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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

**7. MARKETING AUTHORISATION HOLDER**

Zoetis UK Limited  
1st Floor, Birchwood Building  
Springfield Drive  
Leatherhead  
Surrey  
KT22 7LP

**8. MARKETING AUTHORISATION NUMBER**

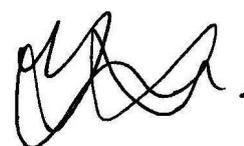
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**9. DATE OF FIRST AUTHORISATION**

13 October 2005

**10. DATE OF REVISION OF THE TEXT**

May 2020



Approved: 01 May 2020