

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Tracherine – Carton**  
**1x 5 doses**

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

Tracherine

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Vaccine containing IBR

**COMPOSITION:**

**Freeze-dried fraction:**

- Live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106,  
minimum  $10^{5.5}$  CCID<sub>50</sub> per dose.

**Diluent:**

- Water for injection.  
- Sodium chloride, 18mg per 2 ml

**3. PHARMACEUTICAL FORM**

Lyophilised nasal powder with sterile diluent for reconstitution.

**4. PACKAGE SIZE**

1 x 5 dose freeze-dried vial + 1 x 5 dose diluent (10 ml)  
1 x 10 ml (5 doses)

**5. TARGET SPECIES**

For cattle

**6. INDICATION(S)**

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

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

**DOSE:** 2ml.

**ROUTE:** Intranasal. Reconstitute the vaccine vial with the entire vial of the sterile diluent.

### **VACCINATION PROGRAMME:**

**Animals older than 10 weeks of age:** A single dose of vaccine should be administered.

**Animals from 3 to 10 weeks of age:** Two doses of vaccine at least 14 days apart. Animals should be revaccinated every 6 months in order to maintain immunity.

## 8. WITHDRAWAL PERIOD

**WITHDRAWAL PERIOD:** Zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

**Consult the package leaflet for further information, contra-indications and warnings etc.**

## 10. EXPIRY DATE

EXP date:

Reconstituted vaccine should be used immediately.

## 11. SPECIAL STORAGE CONDITIONS

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

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**Consult the package leaflet for further information, contra-indications and warnings etc.**

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 42058/4156

**17. MANUFACTURER’S BATCH NUMBER**

Lot No:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Tracherine – Carton**  
**20x 5 doses**

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

Tracherine

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Vaccine containing IBR

**COMPOSITION:**

**Freeze-dried fraction:**

- Live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106,  
minimum  $10^{5.5}$  CCID<sub>50</sub> per dose.

**3. PHARMACEUTICAL FORM**

Lyophilised nasal powder with sterile diluent for reconstitution.

**4. PACKAGE SIZE**

20 x 5 dose freeze-dried vials

**5. TARGET SPECIES**

For cattle

**6. INDICATION(S)**

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

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

**DOSE:** 2ml.

**ROUTE:** Intranasal. Reconstitute the entire contents of the freeze-dried vial with the entire contents of the diluent vial.

### **VACCINATION PROGRAMME:**

**Animals older than 10 weeks of age:** A single dose of vaccine should be administered.

**Animals from 3 to 10 weeks of age:** Two doses of vaccine at least 14 days apart. Animals should be revaccinated every 6 months in order to maintain immunity.

## 8. WITHDRAWAL PERIOD

**WITHDRAWAL PERIOD:** Zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

**Consult the package leaflet for further information, contra-indications and warnings etc.**

## 10. EXPIRY DATE

Expiry date:  
Reconstituted vaccine should be used immediately.

## 11. SPECIAL STORAGE CONDITIONS

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

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**Consult the package leaflet for further information, contra-indications and warnings etc.**

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 42058/4156

**17. MANUFACTURER'S BATCH NUMBER**

Batch No:



**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Tracherine – Vial label**  
**5 doses**

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

Tracherine  
For cattle

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**COMPOSITION:**

**Freeze-dried fraction:**

- Live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106,  
minimum  $10^{5.5}$  CCID<sub>50</sub> per dose.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

5 doses

**4. ROUTE(S) OF ADMINISTRATION**

For intranasal administration.

**5. WITHDRAWAL PERIOD**

**Withdrawal period:** Zero days

**6. BATCH NUMBER**

Lot No:

**7. EXPIRY DATE**

Exp date:

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

Keep out of reach of children

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

**For full instructions see package leaflet.**

**MA Holder:**

Zoetis UK Limited, Surrey

To be supplied only on veterinary prescription.

Vm 42058/4156

POM-V

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:  
Tracherine**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER  
AND OF THE MANUFACTURING AUTHORISATION HOLDER  
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tracherine

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER  
INGREDIENT(S)**

A freeze-dried pellet, each dose containing live attenuated Infectious Bovine Rhinotracheitis (IBR) virus strain ts RLB 106, minimum  $10^{5.5}$  CCID<sub>50</sub>\* supplied together with a vial of sterile diluent for reconstitution. Traces of neomycin sulphate and gentamycin sulphate (not exceeding 25 µg) are present in the final product.

\* Cell Culture Infectious Dose 50

**4. INDICATION(S)**

For the active immunisation of calves and growing cattle to reduce viral shedding and clinical signs caused by Infections Bovine Rhinotracheitis (Bovine Herpesvirus type I) Onset of immunity occurs by 4 days after vaccination.

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

**5. CONTRAINDICATIONS**

Do not vaccinate unhealthy animals.

**6. ADVERSE REACTIONS**

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

## 7. TARGET SPECIES

Calves and growing cattle.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Reconstitute the entire contents of the vaccine vial with all of the sterile diluent using the needle and syringe provided. For each animal, withdraw 2ml of reconstituted vaccine, substitute the nasal applicator for the needle and administer 2ml 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.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Store and transport vaccine between +2°C and +8°C away from light. Do not freeze. Keep out of reach of children.

## 12. SPECIAL WARNING(S)

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

No post vaccination reactions other than those listed above have been observed with ten times overdose with Tracherine.

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.

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

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

Tracherine can be used during pregnancy.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

## 15. OTHER INFORMATION

For animal treatment only.

**LEGAL CATEGORY** POM-V To be supplied only on veterinary prescription.

### PACKAGE QUANTITIES

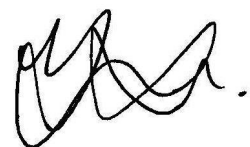
Packs containing a 5 dose vial together with a vial containing 10 ml of sterile diluent.

Also supplied in a cardboard carton containing 20 x 5 dose vials supplied together with 20 x 10ml vials of sterile diluent. Not all pack sizes may be marketed.

Needles and syringes for reconstitution and nasal applicators for vaccination are provided in separate accessory packs.

### MARKETING AUTHORIZATION NUMBER

Vm 42058/4156



Approved: 01 May 2020