

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tuberculin PPD Kit

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Bovine Tuberculin PPD 3000:

Per 0.1 ml (1 dose):

**Active substance:**

Bovine Tuberculin purified protein derivative from culture of *Mycobacterium bovis*, strain AN5: 3000 IU\*

**Excipients:**

Qualitative composition of excipients and other constituents
Phenol
Glucose anhydrous
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Avian Tuberculin PPD 2500:

Per 0.1 ml (1 dose):

**Active substance:**

Avian Tuberculin purified protein derivative from culture of *Mycobacterium avium* subspecies *avium*, strain D4ER: 2500 IU\*

**Excipients:**

Qualitative composition of excipients and other constituents
Phenol
Glucose anhydrous
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections
Ponceau 4R (E124)

(\*IU: International Units according to Ph. Eur.)

Solution for injection.

Bovine Tuberculin PPD 3000 is a clear, colourless to light yellow aqueous solution with a pH between 6.5 and 7.5. Avian Tuberculin PPD 2500 is a clear, red aqueous solution with a pH between 6.5 and 7.5.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Cattle.

#### **3.2 Indications for use for each target species**

To be used for the *in vivo* identification of cattle which have been exposed to *Mycobacterium* species causing bovine tuberculosis. Simultaneous administration of Bovine Tuberculin PPD 3000 and Avian Tuberculin PPD 2500 and comparing the degree of skin swelling of the two injection sites enables differentiation between the specific reaction in target species exposed to *Mycobacterium* species causing bovine tuberculosis and the non-specific reaction in target species, which have been exposed to other species of *Mycobacteria* or related genera, causing cross sensitisation to Bovine Tuberculin PPD 3000.

#### **3.3 Contraindications**

None.

#### **3.4 Special warnings**

For a reliable result of the Single Intradermal Comparative Cervical Tuberculin (SICCT) test the use of the veterinary medicinal product in cattle should be avoided within 42 days following a previous administration of tuberculin PPDs. In specific circumstances, a time interval shorter than 42 days may not be avoided e.g. when a herd undergoing test may include recently acquired (and tested) animals. However, it has been observed that a shorter time interval between tests results in a potential loss of skin responsiveness and is therefore not recommended.

The reliability of the test depends upon the proper intradermal injection of the tuberculin PPDs (Bovine and Avian Tuberculin PPDs) together with the accurate measurement, characterisation, and comparison of the skin reactions 72 hours later. Subcutaneous instead of intradermal injection of tuberculin PPDs may give rise to a false result and is also likely to lead to desensitisation of the animal for a variable period.

The reliability of the test is also influenced by the site of injection of the tuberculin PPD (see 3.9) and by the amount of tuberculin PPD administered; doses less than the prescribed amount of 0.1 ml are likely to lead to a false result of the SICCT test.

The sensitivity of the test can be influenced by concurrent infection with *Mycobacterium* species that do not cause bovine tuberculosis. The interval since infection with *Mycobacterium* species causing bovine tuberculosis, either where an immune response has not had sufficient time to develop, or where the immune response period has been superseded, might also contribute to a lower sensitivity. Notice must be taken that the response is ordinarily somewhat depressed in the peri-parturient period. In the event of a fulminating infection a response to the intradermal test can even be absent.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Not applicable.

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

In case of accidental self-injection persons who have been exposed to tuberculin protein, either from a previous tuberculosis vaccination, or from environmental exposure may expect a reaction. Over 48 to 72 hours this will cause a skin reaction of a hard, dense wheal. Mild itching, swelling, or irritation at the site of the injection are frequent reactions. If a strong reaction or systemic symptoms occur seek medical advice immediately. Show the package leaflet or the label to the physician.

#### Special precautions for the protection of the environment:

Not applicable.

#### Other precautions:

Disease spread precautions.

Personal protective equipment consisting of suitable protective clothing and footwear should be worn when conducting tuberculin tests. All practicable measures of cleaning and disinfection of protective clothing, footwear, hands and equipment (syringes, etc.) should be undertaken on entry and exit from the holding to minimise the risk of disease transfer.

### 3.6 Adverse events

Target species: Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling *
Uncommon (1 to 10 animals / 1,000)	Elevated temperature**

animals treated):	
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\* Shortly after administration, in particular in cattle infected with *Mycobacterium bovis*. In uninfected animals this swelling will greatly decrease in size within 24 hours and completely disappear within 3 to 4 days. In infected cattle and/or in cattle sensitised with non-specific mycobacteria the initial swelling, in uncommon cases up to 65mm, will also decrease in size within 24 hours but it will take up to 4 weeks before the swelling has completely disappeared.

\*\* In infected cattle, will return to normal within 24 hours

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

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

#### Pregnancy, lactation and fertility:

Although no specific laboratory safety tests were done in pregnant or lactating cattle, experience from field use indicate that the administration of Bovine and/or Avian Tuberculin PPD does not have a negative effect on reproductive performance or lactation.

### **3.8 Interaction with other medicinal products and other forms of interaction**

Injection of other products at or adjacent to the site of tuberculin PPD injection should be avoided during the period immediately prior to tuberculin PPD injection and until the completion of the reading of the tuberculin test. Possible reactions due to such other products could be confused with, or otherwise affect, the delayed type hypersensitivity reaction due to the administration of tuberculin PPDs.

Where administration of a medicinal product is necessary such product should not be administered near to the injection sites of Tuberculin PPD Kit and preferably not on the same side of the neck.

In general it is recommended that no other veterinary medicinal product should be administered before and after administration of Tuberculin PPD Kit.

In particular, the veterinary medicinal product should not be used in cattle which recently have been treated with immunosuppressive medicines such as glucocorticosteroids since such a treatment may influence the results of the tuberculin test.

A more severe interpretation of the tuberculin skin test may be required in animals vaccinated against Johne's Disease (paratuberculosis), as vaccination could give rise to false negative SICCT test results in such animals.

N.B. Vaccination of cattle against bovine tuberculosis is currently forbidden in the European Union.

### 3.9 Administration routes and dosage

#### Selection of sites of injection:

The approved injection sites are situated at the border of the anterior and middle thirds of either side of the neck. In adult animals the upper site is about four inches (10 cm) below the crest. The lower site should be about five inches (12.5 cm) from the upper site, on a line drawn parallel with the line of the shoulder. In young animals where there is insufficient space to inject both tuberculin PPDs into the same side of the neck, the tuberculin PPDs should be injected, one on each side of the neck, at corresponding sites in the centre of the middle third of the neck. In animals, which have non-associated lumps or swellings proximal to the injection site(s) the tuberculin PPD should be injected into the opposite side of the neck.

#### Preparation of sites of injection:

The selected sites of injection should be clipped (an adequately sized area for identification of the injection sites), cleansed (with water alone) if obviously dirty, and debris should be removed prior to injection. The presence of any abnormalities near to the injection site(s) should be recorded. The presence of skin tuberculosis should also be recorded.

#### Measurement of skin thickness prior injection:

Before injection, a fold of skin at each of the intended injection sites and within the clipped area must be taken between the forefinger and thumb and accurately measured to the nearest millimetre using callipers.

#### Intradermal injection:

A correct intradermal injection technique and the delivery of the prescribed dose volume of 0.1 ml per injection are important for a reliable test result. A correct injection is confirmed by palpating a small pea-like swelling at each injection site. If there is any doubt about either of the injections being delivered intradermally, a further injection should be made, preferably at a corresponding site on the other side of the neck.

#### Reading of the tuberculin test after injection:

The injection sites should be palpated carefully to detect reactions 72 hours (+/- 4 hours) after intradermal injection and the skin-fold thickness of each injection site re-measured. The same person should measure the skin before the injection and when the test is read.

Measurements of the injection site must be taken carefully by placing the callipers, where a response (swelling) has been detected, across the broadest width of the swelling, without applying undue pressure.

Clinical signs compatible with bovine tuberculosis must be recorded at the time of reading to assist in the identification of animals that may be exposed but which have not been identified as reactors in the SICCT test (i.e. false negatives).

The presence of clinical signs, 72 hours after injection of tuberculin PPD, such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the regional (pre-scapular) lymph nodes, is indicative of likely exposure to *Mycobacterium* species causing bovine tuberculosis (i.e., a member of the *Mycobacterium tuberculosis* complex). The person

performing the test should carefully examine and record any such signs. Especially in case of necrosis in absence of any other clinical signs that are symptomatic of bovine tuberculosis, the tester should be cautious in making the correct interpretation. In case of doubt the competent authority may require additional diagnostic measures.

Interpretation of the Single Intradermal Comparative Cervical Tuberculin (SICCT) test:

For the establishment and maintenance of officially tuberculosis-free herd status for the purpose of internal EU trading in bovines, the interpretation of the skin reactions induced by the bovine and avian tuberculin PPD injections should be made according to the guidelines (“Intradermal Tuberculin Skin Test Protocol in Bovine Animals”) published by the EU Reference Laboratory for bovine tuberculosis at:

<https://www.visavet.es/bovinetuberculosis/databases/protocols.php>

<b>Interpretation of skin reactions of the SICCT test</b>	<b>Clinical observations and the recorded increases in skin-fold thickness at the sites of injection 72 hours after injection of the Tuberculin PPDs.</b>
Positive reaction	A reaction to bovine tuberculin PPD which is more than 4 mm greater than the reaction to avian tuberculin PPD, or the presence of clinical signs.
Inconclusive reaction	A reaction to bovine tuberculin PPD (of at least 2 mm) which is from 1 to 4 mm greater than the reaction to avian tuberculin PPD, and the absence of clinical signs.
Negative reaction	A reaction to bovine tuberculin PPD which is equal to or less than the reaction to avian tuberculin PPD, and the absence of clinical signs.

Animals inconclusive to the SICCT test that are not removed, either voluntarily by the animal owner or by the competent authority, shall be subjected to another test after a minimum of 42 days. Animals, which are not negative to this second test, shall be deemed positive to the test.

National requirements for a more severe interpretation of the skin reactions may apply.

**3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

The reactions seen after administration of an overdose are the same as those described under 3.6.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

### **3.12 Withdrawal periods**

Zero days.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

Bovine Tuberculin PPD 3000: QI02AR01  
Avian Tuberculin PPD 2500: QI02AR02

These products are *in vivo* diagnostic substances to diagnose the state of immunity of cattle against bovine tuberculosis.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Do not mix with any other veterinary medicinal product.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale:  
The veterinary medicinal product comprises two components with the following shelf-lives:

Bovine Tuberculin PPD 3000:

- 20-doses presentation: 4 years
- 50-doses presentation: 4 years

Avian Tuberculin PPD 2500:

- 20-doses presentation: 4 years
- 50-doses presentation: 4 years

The shelf-life of the veterinary medicinal product is specified as the shelf-life of the component with the earliest expiry date.

Shelf life after first opening the immediate packaging:  
Use immediately.

### **5.3 Special precautions for storage**

Store in a refrigerator (2 °C - 8 °C).

Do not freeze.

Keep the vials in the polystyrene box, closed with carton sleeve, in order to protect from light.

Transportation:

May be transported at 2 °C - 37 °C for a period not longer than 14 days.

Do not freeze.

Keep the vials in the polystyrene box, closed with carton sleeves, in order to protect from light.

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

The 20-doses presentation of the veterinary medicinal product :

Polystyrene box with 20 vials (hydrolytic Type I) of Bovine Tuberculin PPD 3000 and 20 vials (hydrolytic Type I) of Avian Tuberculin PPD 2500. Each vial contains 20 doses of 0.1 ml.

The 50-doses presentation of the veterinary medicinal product :

Polystyrene box with 10 vials (hydrolytic Type I) of Bovine Tuberculin PPD 3000 and 10 vials (hydrolytic Type I) of Avian Tuberculin PPD 2500. Each vial contains 50 doses of 0.1 ml.

The vials are closed with a rubber-butyl stopper and sealed with an aluminium cap (blank cap for Bovine Tuberculin PPD 3000 and red cap for Avian Tuberculin PPD 2500). The box is closed with a labelled carton sleeve. A package leaflet is included.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Prionics Lelystad B.V.

**7. MARKETING AUTHORISATION NUMBER**

Vm 36410/4000

**8. DATE OF FIRST AUTHORISATION**

24 November 2010

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

September 2025

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

Approved 11 November 2025

*Gavin Hall*