

**I SUMMARY OF PRODUCT CHARACTERISTICS****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

INTERTEST™ Avian PPD Tuberculin

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION****Active substance:**

Tuberculin purified protein derivative (PPD) of *Mycobacterium avium*, strain D4. Per dose (0.1 ml): 2500 IU.

**Preservative:**

Phenol: ≤ 0.5%

**3. PHARMACEUTICAL FORM**

Aqueous solution

**4. CLINICAL PARTICULARS****4.1 Target animals**

Cattle, sheep, goats, pigs

**4.2 Indication for use**

Diagnosis of avian tuberculosis and comparative tuberculin test in cattle and other domestic mammals.

**4.3 Contra-indications:**

Do not use in animals suffering from an acute illness.

**4.4 Special warnings**

In order to prevent inflammatory reactions the test should be administered aseptically.

A follow-up test in case of inconclusive reactions should be done not earlier than 6 weeks after a previous test as sometimes false positive reactions can occur.

In case of an infection with a *Mycobacterium* from another species, non-specific reactions may occur. In order to distinguish these from a specific reaction to *M. bovis* an intracutaneous comparative test with bovine and avian tuberculin can be done.

**4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals**

On rare occasions latently infected animals or sensitized animals may show allergic or anaphylactic reactions when injected with tuberculin.

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

**4.6 Adverse reactions**

Side effects, other than the local reactions that can be expected, should be reported to the veterinary surgeon in charge.

**4.7 Use during pregnancy and lactation**

No restrictions.

**4.8 Interaction with other medication**

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In order to prevent a false negative reaction, animals treated with for example corticosteroids or ACTH should be excluded from testing.

False negative reactions can not be excluded after administration of life virus vaccines. False positive reaction may occur in BCG-vaccinated animals.

**4.9 Amounts to be administered and administration route**

The intradermal tuberculin test (single or comparative test) is performed according to official local or national procedures. A correct injection technique is important.

Recommended site for the intracutaneous injection in cattle is mid-neck in front of the spine of the scapula.

When both avian and bovine tuberculins are injected in the same animal (comparative test), the site for injection of avian tuberculin shall be about 10 cm from the crest of the neck and the site for the injection of bovine tuberculin about 12.5 cm lower on a line roughly parallel with the line of the shoulder or on different sides of the neck; in young animals in which there is not room to separate the sites sufficiently on one side of the neck, one injection shall be made on each side of the neck at identical sites in the centre of the middle third of the neck.

The comparative tuberculin test should be performed not earlier than 6 weeks after the single intradermal test. Otherwise false-positive reactions may appear.

*Technique*

The injection site must be clipped and cleansed and may not show any kind of swelling or other changes.

A fold of skin shall be taken between the forefinger and thumb and measured with callipers and recorded. The dose of tuberculin (0.1 ml) shall then be injected by a method that ensures that the tuberculin is delivered intradermally and not subcutaneously and that no injection fluid flows back. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin, inserted obliquely into the deeper layers of the skin may be used. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection.

*Interpretation of reactions*

The interpretation of reactions shall be based on clinical observations and the recorded increase in skin-fold thickness at the sites of injection 72 hours after injection of tuberculin.

(a) Positive reaction: an increase in skin thickness at the bovine site of injection which is more than 4 mm greater than the reaction at the site of avian injection, or the presence of clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.;

(b) Inconclusive reaction: an increase in skin thickness at the bovine site of injection which is 1 to 4 mm greater than the reaction at the site of avian injection and the absence of clinical signs;

(c) Negative reaction: an increase in skin thickness at the bovine site of injection which is less than or equal to the reaction at the site of avian injection and the absence of clinical signs.

Animals inconclusive to the intradermal comparative test shall be subjected to another test after a minimum of 42 days. Animals, which are not negative to this second test, shall be deemed to be positive to the test.

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

Not known respectively not necessary.

**4.11 Withdrawal period**

0 days.

**5 IMMUNOLOGICAL PROPERTIES**

INTERTEST Avian PPD Tuberculin is used for the diagnosis of avian tuberculosis and comparative tuberculin test in cattle and other domestic mammals.

ATC vet code: QI02AR02

**6. PHARMACEUTICAL PARTICULARS****6.1 Incompatibilities**

Do not mix with any other immunological product.

**6.2 Shelf life**

24 months.

After broaching the vial, use immediately.

**6.3 Special precautions for storage**

Store in a refrigerator (2° - 8°C).

Do not freeze.

Protect from light.

**6.4 Nature and composition of immediate packaging**

Clear glass vials containing 20 doses or glass carpules containing 18 doses.

Not all presentations may be marketed.

**6.5 Special precautions for disposal of unused product or waste material:**

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

**PRODUCT OF INTERVET INTERNATIONAL BV  
BOXMEER - THE NETHERLANDS**

Manufactured by:

WDT (Wirtschaftsgenossenschaft deutscher Tierärzte e.G.)

Serumwerk Memsem

27318 Hoyerhagen

Germany