I. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INTERTEST™ Bovine PPD Tuberculin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Tuberculin purified protein derivative (PPD) of *Mycobacterium bovis*, strain AN5. Per dose (0.1 ml): 5000 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

For in-vivo diagnosis of bovine tuberculosis 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 aseptic. 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

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.
For instruction of the comparative test, when both avian and bovine tuberculins are injected in the same animal, see specifications for avian PPD tuberculin product.

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 intradermically 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) Negative reaction: if only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without 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: if no clinical signs such as mentioned in a) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.

(c) Positive reaction: if clinical signs such as mentioned in a) are observed and/or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site.

Animals inconclusive to the single intradermal 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.

Animals positive to the single intradermal test may be subjected to an intradermal comparative test if false positive reaction or interference reaction is suspected.

Any retest should be performed in accordance with the local or national control programmes standard.

Other animals
Tuberculin test in other domestic animals:

An intracutaneous test with 0.1 ml bovine tuberculin can be conducted in sheep, goats, and pigs.
Sheep and goat: The injection site is neck or shoulder.
Pig: Ear basis.

For pigs the comparative test is recommended as often infections with other *Mycobacterium* spp. may interfere.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Not known.

4.11 Withdrawal period
0 days.

5 IMMUNOLOGICAL PROPERTIES
INTERTEST Bovine PPD Tuberculin is used for the diagnosis of bovine tuberculosis in cattle and other domestic mammals.
ATC vet code: QI02AR01

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

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