

LABELLING

Tuberculin PPD Kit

(Bovine Tuberculin PPD 3000 and Avian Tuberculin PPD 2500)

Current version at time of submission of renewal application

(last update: December 7, 2010)

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

(The Tuberculin PPD Kit is a combination of an equal number of vials with Bovine Tuberculin PPD 3000 and Avian Tuberculin PPD 2500 packed in a polystyrene box and fitted with a carton sleeve. The outer packaging is a carton sleeve.)

Carton sleeve upon which a label is attached.

There are two presentations of the Tuberculin PPD Kit:

The 20-doses presentation of the Tuberculin PPD Kit:

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

The 50-doses presentation of the Tuberculin PPD Kit:

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tuberculin PPD Kit

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Bovine Tuberculin PPD 3000

Per 0.1 ml (1 dose):

Bovine Tuberculin PPD from culture of *Mycobacterium bovis*, strain AN5 3000 IU*

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

Phenol 0.4 – 0.5 mg

Avian Tuberculin PPD 2500

Per 0.1 ml (1 dose):

Avian Tuberculin PPD from culture of *Mycobacterium avium*, subsp. *avium*, strain D4ER (*IU: International Units according to Ph. Eur.)

Phenol 2500 IU*

Ponceau 4R (E124) 0.4 – 0.5 mg

5 µg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

For the 20-doses presentation of the Tuberculin PPD Kit:

40 vials:

20 vials Bovine Tuberculin PPD 3000

20 vials Avian Tuberculin PPD 2500

Contents 1 vial: 20 doses of 0.1 ml

For the 50-doses presentation of the Tuberculin PPD Kit:

20 vials:

10 vials Bovine Tuberculin PPD 3000

10 vials Avian Tuberculin PPD 2500

Contents 1 vial: 50 doses of 0.1 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

In-vivo diagnostic kit for bovine tuberculosis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet carefully

Intradermal injection

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

(None)

10. EXPIRY DATE

Exp: MM/YYYY (= expiration date of the Tuberculin PPD Kit)

Should be used immediately after first opening

11. SPECIAL STORAGE CONDITIONS

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

Do not freeze.

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

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

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

(None)

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

For animal treatment only.

To be supplied only on veterinary prescription.

UK only
Vm 36410/4000

POM-V

IE only
VPA 10526/001/001

VPO-1

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Prionics Lelystad BV, Lelystad, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

See section 13

17. MANUFACTURER’S BATCH NUMBER

Lot: XXTUXXXX (= Batch nr. Of Tuberculin PPD Kit)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

(The size of the vial is less than 50 ml and therefore meets the criteria to be regarded as a “small immediate packaging unit”)

The Tuberculin PPD Kit is comprised of 20 (or 10) vials of Bovine Tuberculin PPD 3000 and 20 (or 10) vials of Avian Tuberculin PPD 2500. The immediate package is the glass vial.

Glass vials (hydrolytic Type I) with a content of 20 (or 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).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovine Tuberculin PPD 3000
Solution for injection

Avian Tuberculin PPD 2500
Solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per 0.1 ml (1 dose):

Bovine Tuberculin PPD from culture of *Mycobacterium bovis*, strain AN5 3000 IU*
(*IU: International Units according to Ph. Eur.)

Per 0.1 ml (1 dose):

Avian Tuberculin PPD from culture of *Mycobacterium avium*, subsp. *avium*, strain D4ER 2500 IU*
(*IU: International Units according to Ph. Eur.) 0.4 – 0.5 mg

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

20 doses of 0.1 ml

50 doses of 0.1 ml

4. ROUTE(S) OF ADMINISTRATION

Intradermal injection

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Lot: XXXXXX

7. EXPIRY DATE

Exp: MM-YYYY

Should be used immediately after first opening

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.