

[Version 8, 10/2012]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV BOVINE TUBERCULIN PPD, solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 0.1 ml contains:

Purified protein derivative from culture of *Mycobacterium bovis*, strain AN-5 2,500 IU

Phenol..... 0.5 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ml

10 vials of 5 ml

25 vials of 5 ml

2 ml

10 vials of 2 ml

25 vial of 2 ml

5. TARGET SPECIES

Cattle

6. INDICATIONS

For *in vivo* diagnosis of bovine tuberculosis

7. METHOD AND ROUTES OF ADMINISTRATION

Intradermal use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }

Once opened, use immediately

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Protect from light. Do not freeze.

May be stored and transported up to a maximum of 37 °C for a period not longer than 14 days.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CZ Veterinaria, S.A.
36410 Porriño (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 2 ml or 5 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CZV BOVINE TUBERCULIN PPD

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Purified protein derivative from culture of *Mycobacterium bovis*, strain AN-5 2,500 IU/0.1 ml

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

2 ml (20 doses)

5 ml (50 doses)

4. ROUTES OF ADMINISTRATION

Intradermal use

5. MARKETING AUTHORISATION No.

Withdrawal period: zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {months/year}

Once opened, use immediately

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.